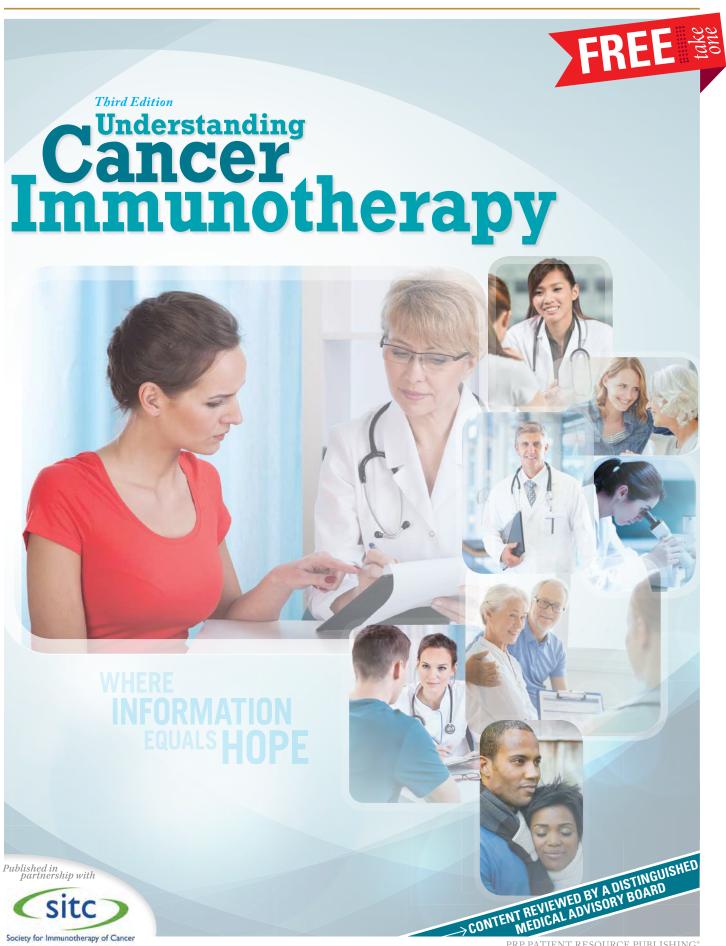
# PATIENT RESOURCE



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Society for Immunotherapy of Cancer

www.sitcancer.org

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# Understanding Cancer Immunotherapy

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I didn't look sick, so I didn't want to act sick.

Having and treating cancer is only one part of your life.

Jane McNee, melanoma survivor

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#### ightarrow The Society for Immunotherapy of Cancer (SITC) is the

world's leading member-driven organization specifically dedicated to professionals working in the field of cancer immunology and immunotherapy. Established in 1984, SITC is a 501(c)(3) not-for-profit organization with a growing constituency of academic, government, industry, clinical and basic scientists and medical professionals from around the world. SITC's mission is to improve cancer patient outcomes



by advancing the science, development and application of cancer immunology and immunotherapy through core values of interaction/integration, innovation, translation and leadership in the field.

Learn more at www.sitcancer.org

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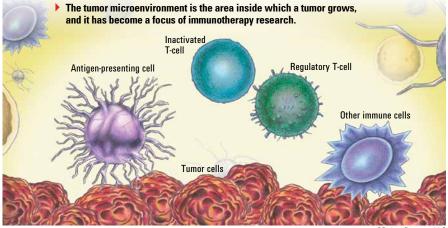
# IMMUNOTHERAPY TODAY

#### ▲ When former President Jimmy

Carter announced that his doctors could no longer find evidence of melanoma in his body, he brought public attention to a ground-breaking type of cancer treatment. One of the treatments he received was immunotherapy, which helps the body's immune system fight cancer. Though the study of immunotherapy is more than a century old, the field has seen rapid advances in the past few years, and it has the potential to dramatically change cancer treatment. In Carter's case, doctors combined an immunotherapy drug with surgery and radiation therapy. Within months, this approach eliminated the cancer in Carter's liver and brain.

Immunotherapy is one of the major focuses of cancer research today, and results like these are being recognized by some very visible advocates. In his 2016 State of the Union speech, President Barack Obama asked Vice President Joe Biden to lead Cancer Moonshot, a plan aimed at making 10 years' worth of progress in cancer research within five

#### **▲ | TUMOR MICROENVIRONMENT**



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years. The Moonshot goals are to improve treatment as well as find cancer earlier and prevent it when possible.

As part of this initiative, the National Cancer Institute (NCI) committed to 10 recommendations a commission of scientists believe will help meet the goal. One of the recommendations is to create a national network of cancer immunotherapy clinical trials, which would help researchers share information as they find and test new treatments. NCI also plans to form a similar

network specifically for pediatric immunotherapy clinical trials to speed the process of testing immunotherapy in children.

Although immunotherapy is making notable progress, the work of researchers continues. The U.S. Food and Drug Administration has approved a number of immunotherapy drugs, with more in the pipeline. Immunotherapy is quickly becoming a standard first-line treatment for some types of cancer, and clinical trials are ongoing in every cancer type.

In addition to showing how immunotherapy can fight cancer, research also focuses on personalizing treatment. Recent studies explore how doctors can best predict outcomes for specific patients with specific drugs. These studies also may help doctors understand why some immunotherapies work for certain people but not for others.

As treatment strategies continue to evolve, some doctors point to prevention as the next big leap toward eliminating cancer. The vaccine for human papillomavirus (HPV), which has been successful at protecting against some cancer strains, might become a model for the development of more vaccines, which could engage the immune system's defenses before cancer begins.

Ask your doctor about immunotherapy and if it is an option for you. The more you know, the more prepared you will be to make informed treatment decisions.

# CANCER VS. THE BODY

In the 1950s, some researchers thought that in addition to protecting your body against bacteria and viruses, the immune system looked for abnormal cells and killed them before they could become tumors. This theory, called cancer immunosurveillance, was initially rejected. In the last 10 years, however, studies have shown that immune cells are indeed important in the prevention of cancer. Although tumors may develop in a functioning immune system, the way a tumor grows and develops is influenced by the body's immune response. Based on this new evidence – and confirmed by mouse tumor studies conducted by Dr. Robert Schreiber – the theory has been renamed "cancer immunoediting."

The three E's of Dr. Schreiber's theory of cancer immunoediting are elimination, equilibrium (balance) and escape.

**ELIMINATION.** The immune system sees and destroys cancer cells. In this phase, our bodies may be regularly introduced to cancerous changes, and our immune systems are capable of handling and eliminating them.

**EQUILIBRIUM.** If the cancer cells are not destroyed right away, they may exist in a delicate balance between growth and control by the immune system. During equilibrium, the body's immune system is able to keep the cancer cells in check but unable to kill them completely. In this phase, a tumor may remain dormant for an unknown length of time and evade medical testing. According to the theory, however, the constant interactions between the tumor cells and the T-cells of the immune system may lead to tumors that can adapt to the immune response (see page 2 for more information). This means the immune system may no longer be able to find tumors and attack them. Tumors that avoid the immune response can no longer be controlled and move on to the third phase.

**SECAPE.** The escape phase refers to the disruption of equilibrium that leads to immunosuppression. This allows tumors to escape and begin growing in an environment of immune "tolerance." It's at this point that the symptoms of cancer begin to appear. Tumors in the escape phase use a number of methods to alter the body's immune response in a way that allows them to grow.

#### ADDITIONAL RESOURCES

- Cancer Research Institute: www.cancerresearch.org Immunotherapy and Chemotherapy: What's the Difference?
- National Cancer Institute: www.cancer.gov Immunotherapy: Using the Immune System to Treat Cancer
- Society for Immunotherapy of Cancer: www.sitcancer.org

# THE IMMUNE SYSTEM

### Immunotherapy uses the same

natural defenses your body uses every day to fight infection. However, your body's immune system isn't always able to handle something as intense as cancer on its own, so doctors build on the healing capabilities of your immune system with immunotherapy.

#### **UNDERSTANDING THE IMMUNE SYSTEM**

The immune system is the body's natural defense against infection and disease, protecting the body from harmful substances, such as bacteria, viruses (also called germs) and cancer. The cells of the immune system continuously flow through the body, looking for germs that may be invading the body. The immune system recognizes invaders by their antigens, which are proteins on the surface of the invading cells (see Figure 1).

Every cell or substance has its own specific antigens, and a person's cells carry "selfantigens" that are unique to that individual. People carry self-antigens on normal cells, such as liver, colon and thyroid cells. Cells with self-antigens are typically not a threat. Invading germs, however, do not come from within the body, so they do not carry self-antigens. Instead, they carry "nonselfantigens." The immune system is designed to identify cells with nonself-antigens as harmful and respond appropriately. Most immune cells release cytokines (messengers) to help them communicate with other immune cells and control the response to any threats.

Your immune system is always working to keep your body free from infection. Your skin is your immune system's first barrier. When you skin your knee, you break that barrier, and harmful substances can easily enter the

body (see Figure 2). As soon as this happens, immune cells in the injured tissue begin to respond and also call other immune cells that have been circulating in your body to gather at the site and release cytokines to call even more immune cells to help defend the body against invasion. The immune cells recognize any bacteria or foreign substances as invaders. Immune cells, also called natural killer cells, begin to destroy the invaders in a general attack. Although this attack can kill some of the invaders, it may not be able to destroy all of them or prevent them from multiplying.

At the same time, other immune cells called dendritic cells start to "eat" the invaders and their nonself-antigens. This process causes the dendritic cells to transform into antigenpresenting cells (APCs). These APCs expose the invader cells to the primary immune cells of the immune system — the B and T-cells so that these cells can recognize the invading cells. B-cells work rapidly to produce antibodies that help identify and stop the invading bacteria cells. Viruses, unlike bacteria, like to hide inside normal cells and may be harder for the immune system to recognize.

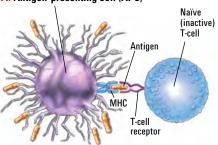
T-cells are designed to find abnormal fragments of viruses inside normal cells. Before these T-cells have been activated to fight viruses and other invaders, they're known as "naïve" T-cells. APCs communicate with and activate the naïve T-cells by connecting to them through protein molecules on their surfaces. A specific set of proteins on the APC, called the major histocompatibility complex (MHC), must connect to the receptor on each T-cell. This first important connection is sometimes referred to as Signal 1. This connection allows the T-cell to recognize antigens on invading cells as a threat.

Before a T-cell can be fully activated, however, additional molecules on the surfaces of both cells must also be connected to

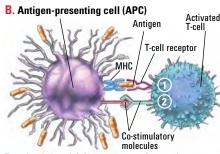
broken.

# **▲ | T-CELL ACTIVATION**

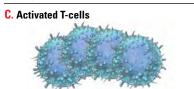
# A. Antigen-presenting cell (APC)



Inactive T-cells are activated when antigen-presenting cells (APCs) connect with the T-cell.



Two signals (see 1 & 2) are necessary for complete activation.

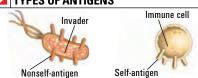


Activated T-cells then multiply to defeat the threat.

confirm that an attack against the invader is necessary. This second signal is known as the co-stimulatory signal, or Signal 2. If a T-cell receives Signal 1 but not Signal 2, the T-cell will die, and the attack is shut down before it even starts.

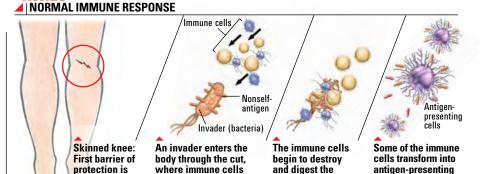
When a T-cell receives both Signal 1 and Signal 2, it is able to recognize the invading cells and destroy them. This fully activated T-cell then multiplies to develop an army of T-cells that is equipped with the necessary weapons to defeat the threat (see Figure 3).

# TYPES OF ANTIGENS



All cells, including normal body cells, have antigens, or proteins, on their surface. Self-antigens are proteins that are specific to an individual person, and cells with self-antigens are usually not a threat to the body. People carry self-antigens on normal cells, such as liver, colon and thyroid cells. However, invading cells are not part of the body and so do not have self-antigens. Instead, these cells have nonself-antigens. The immune system can identify cells with nonself-antigens as harmful and begin an attack on those cells.

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invader and its

antigens.

have begun to gather

to protect the body.

immune cells about @Patient Resource LLC

cells that tell other

the invader.

Multiple generations of immune cells are created by the same immune response, and then some T-cells transform into regulatory T-cells, which work to slow and shut down the immune response once the threat is gone.

Other T-cells may become memory T-cells. Memory T-cells can stay alive for years, continuing to fight off the same invading cells. Memory is the basis of immune protection against disease in general and explains why we don't become infected with some diseases, such as measles or chicken pox, more than once.

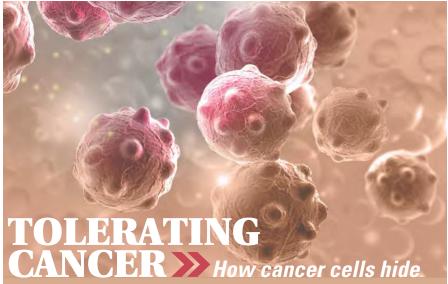
#### **FACING CANCER**

Your immune system basically attacks cancer in the same way, but the process is more complicated because cancer cells are created by the body. Because of this, the normal ways to find and fight invading cells from outside the body aren't always effective. If the body can't tell the difference between tumor cells and normal cells, the tumor cells may be able to "hide" from the immune system (see *Tolerating Cancer*).

Sometimes, the DNA abnormalities (mutations) that cause cancer may be different enough to stimulate an immune response similar to the response described for invading virus cells. If the immune system detects the cancer, the APCs show cancer cell materials to T-cells, the primary players in the fight against cancer. The MHC on APCs must connect to receptors on T-cells, and the T-cells must receive both Signal 1 and Signal 2 to become activated and multiply. If Signal 2 is not received, the response will shut down. A T-cell can function properly against the cancer only if it recognizes the cancer as harmful, receives the proper signals to become activated, and continues to get signals to continue the attack.

Tumor cells can create cytokines, which means that cancer cells can communicate with and confuse other immune cells, allowing the cancer to take control of certain parts of the process that the body uses to regulate the immune response. So, even if the immune system recognizes the cancer, it may not be able to successfully start or maintain an attack long enough to kill the cancer cells.

Researchers continue to investigate immunotherapy strategies, and the ability of T-cells to become activated and attack cancer is at the heart of that research. One area of research focuses on how cancer cells can trick the immune system into turning on "checkpoint pathways" early. Checkpoint pathways are part of the system of checks and balances that allow immune cells to evaluate the attack



To understand how cancer cells are able to evade detection, think of suffering from a pollen allergy. Your doctor may give you allergy shots to relieve the symptoms, such as sneezing and watery eyes. You receive increasing doses of a specific allergen over a series of visits to the doctor, which causes your body to develop a tolerance to pollen. This type of therapy can provide temporary or permanent relief of symptoms. Your body no longer sees the pollen as an invader, so your immune system stops attacking it. This situation is similar to what can happen with cancer cells.

In early stages, cancer cells may shed proteins into the body. As these proteins circulate through the bloodstream, your body begins to develop a tolerance for the cancer cells. Just like your body no longer sees pollen as an invader, the immune system may not recognize these cancer cells as a threat. Then, just like the pollen, the cancer cells may be safe from an immune system attack.

Immunotherapy seeks to reverse this tolerance, to once again identify the cancer cells as a threat and a target for destruction.

against the threat at multiple stages. The pathways essentially function as the "brakes" when the body determines the response is no longer needed. By using signals to confuse other immune cells into putting on the brakes, the cancer can shut down the attack before it has responded effectively and allow the cancer cells to continue to grow. Blocking the effect of these checkpoint pathways can restore the normal function of the immune cells.

The longer the cancer cells face a weakened immune response, the more they're able to adapt, and the easier it is for them to manipulate immune cells inside the tumor's location (sometimes called the microenvironment). This area typically contains cancer cells, normal connective tissues that form the structure of the tumor, access to blood vessels that drive tumor growth and several cell types that contribute to tumor development. Immune cells found in this area are often referred to as tumor-infiltrating lymphocytes (TILs). Because the tumor can control cells in the microenvironment, the tumor can trick TILs into becoming useless or even helping the tumor grow. For example, APCs in the tumor microenvironment may be confused by signals from tumor cells, preventing the APCs from functioning properly and making them incapable of sounding the alarm about a threat. In some cases, tumors can upregulate (increase) the activity of regulatory T-cells inside the area. With this increased activity, regulatory T-cells are actually working to reduce the immune response around the tumor by turning off the other cancerfighting T-cells. It's as if the tumor recruits the body's own immune cells to fight off the attack, using the very processes that normally protect the body. The longer the immune system is exposed to the tumor, the weaker the immune response becomes. Immunotherapy research focuses on identifying different ways tumors manipulate the immune system and how to reverse those processes. ■

### ADDITIONAL RESOURCES

- ► American Cancer Society: www.cancer.org
  Cancer Immunotherapy
- American Society of Clinical Oncology: www.cancer.net Understanding Immunotherapy
- Society for Immunotherapy of Cancer: www.sitcancer.org Patient Information

# IMMUNOTHERAPY STRATEGIES

# ✓ Immunotherapy is among one of

the newest approaches to treating cancer. Immunotherapy is based on the understanding that cancer cells can hide from the immune system through multiple techniques. Different immunotherapies help restore the immune system's ability to find and destroy tumors in various ways. Research into immunotherapy is rapidly expanding, and clinical trials with current and in-development drugs are underway.

Immunotherapy differs from these other cancer treatments.

- Chemotherapy, which uses drugs to kill rapidly multiplying cells, including cancer cells and sometimes healthy cells, as well.
- **Radiation therapy,** which targets a specific region of the body with high-energy X-rays to destroy cancer cells.
- Targeted therapy, which may target the internal components and function of the cancer cell, the receptors on the outside of the cancer cell or the blood vessels that supply oxygen to the cancer cell.

Immunotherapy is a type of targeted therapy. The difference between targeted therapy and immunotherapy is that targeted therapies work directly on the tumor while immunotherapies work to boost the immune system to attack the cancer.

Immunotherapy depends on a functioning immune system, so it is important to make sure that you do not have an autoimmune disorder or are not taking any immunosuppressive medications. After taking into consideration these and other factors, such as your overall health, type and stage of your cancer and your treatment history, your doctor may recommend one or a combination of treatments.

Not everyone is a candidate for immunotherapy. If immunotherapy is not suggested for you, do not be disappointed; many other treatments are available. In addition, you may be a candidate for a clinical trial that offers access to a leading-edge treatment that is not yet available to all (see page 16). Ask your doctor about all your options, taking into consideration possible side effects, before making any treatment decisions.

Immunotherapy has the potential to remain effective for long intervals far beyond the end of treatment — a feature called "memory." Memory is the same feature that allows a tetanus vaccine, for example, to remain effective for many years. This effect can lead to long-term, cancer-free remission and increased overall survival. Because it's less likely that immunotherapy will affect healthy tissues and cells, side effects may be less common and either less severe or more easily treatable for some people. As with any treatment, however, there are still associated risks that should be discussed with your doctor.

Once treatment begins, monitoring is key. More monitoring and follow-up occur with immunotherapy than with most other forms of treatment. You will likely undergo testing to allow your doctor to evaluate how well treatment is working by measuring the size of the tumor as treatment progresses.

Several different immunotherapy strategies are currently being studied or used as cancer treatments, including the following.

#### ADOPTIVE T-CELL TRANSFER (T-CELL THERAPY)

Adoptive T-cell transfer involves enhancing the body's own T-cells to fight cancer. There are two main types of adoptive cell transfer immunotherapy. One type involves the doctor isolating T-cells from a patient's tumor (tumor-infiltrating lymphocytes, or TIL), expanding them to large numbers, and then administering them to patients. In the second strategy, T-cells collected from the patient are engineered with new receptors (chimeric antigen receptor T-cells, or CAR-T) to recognize specific antigens on the surface of cancer cells, and then infused back into the patient. In both cases, the T-cells multiply, seek and destroy the cancer cells that carry those specific antigens.

This type of immunotherapy is still investigational and available only through clinical trials. Studies have shown promise in the treatment of leukemia, lymphoma, metastatic melanoma, neuroblastoma and synovial cell sarcoma.

#### **IMMUNE CHECKPOINT INHIBITORS**

Immune checkpoint pathways are specific connections between molecules on the surfaces of immune cells — specifically between antigen-presenting cells and T-cells, or between T-cells and tumor cells — that help regulate the immune response. Some tumor cells have proteins on their surface that bind to activated immune cells and inhibit their function. This connection effectively puts the brakes on the attack (known as tumor-induced immunosuppression).

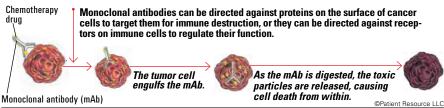
Immune checkpoint inhibitors are drugs that block the checkpoint from being engaged, which essentially turns the immune response back on. These immune checkpoint inhibitors currently are being used to treat cancer.

- Anti-CTLA-4 antibodies block the connection necessary to engage the CTLA-4 protein, allowing the T-cells to continue fighting cancer cells instead of shutting down the immune response. CTLA-4 is a protein receptor found on the surface of T-cells. When activated, CTLA-4 is capable of suppressing the immune system response. Anti-CTLA-4 drugs prevent this from happening.
- Anti-PD-1 drugs block the connection necessary to engage the PD-1 protein, allowing the T-cells to continue their response against cancer cells. The PD-1 checkpoint pathway is one of several pathways for putting the brakes on the T-cells. When the PD-1 receptors on the surface of T-cells connect with the PD-1 ligand (PD-L1) on the surface of cancer cells or other immune cells, signals are sent to the T-cells to slow down the response. Anti-PD-1 drugs prevent this from happening.
- Anti-PD-L1 molecules bind to the PD-1 proteins on the T-cell and turn them off. Cancer cells have the ability to make certain molecules appear on the surface, including PD-L1 and PD-L2 of the PD-1 checkpoint pathway. Cancer cells may also cause immune cells near the cancer to express PD-L1. Anti-PD-L1 molecules allow T-cells to attack the cancer cells.

#### MONOCLONAL ANTIBODIES

One of the body's natural immune responses to





foreign substances is the creation of antibodies specific to the antigens found on the surface of invading germ cells. Some antibodies can recognize portions of proteins on the surface of cancer cells. Researchers can design antibodies that specifically target a certain antigen.

Monoclonal antibodies (mAbs) are antibodies made in a laboratory that are designed to target specific tumor antigens. Also, mAbs can work in different ways, such as flagging targeted cancer cells for destruction, blocking growth signals and receptors or delivering other therapeutic agents directly to targeted cancer cells. They also can be created to carry cancer drugs, radiation particles or laboratorymade cytokines (proteins that enable cells to send messages to each other) directly to cancer cells (see Figure 1). When a mAb is combined with a toxin, such as a chemotherapy drug, it travels through the system until it reaches the targeted cancer cell, where it attaches to the surface, gets swallowed by the tumor cell and breaks down inside the cell, releasing the toxin and causing cell death. Combining mAbs with radiation particles, a treatment known as radioimmunotherapy, allows for radiation to be delivered in lower doses over a longer period of time directly to specific cancer cells. This direct form of radiation delivery typically damages only the targeted cells.

Three different types of mAbs are used in cancer treatment.

- Naked mAbs work by themselves. No drugs or radioactive particles are attached to them.
- Conjugated mAbs have a chemotherapy drug or a radioactive particle attached to them. The mAb is used to deliver the treatment to the cancer cells. These also are referred to as tagged, labeled or loaded antibodies.
- **Bispecific mAbs** are made up of two different mAbs. They can attach to two different proteins at the same time.

#### NONSPECIFIC IMMUNE STIMULATION

This immunotherapy strategy gives the immune system an overall boost and can be used alone or in combination with other treatments to produce increased and longer-lasting immune responses. Different types of nonspecific immune stimulation include the following.

■ Cytokine immunotherapy aids in communication among immune cells and plays a big role in the full activation of an immune response. Cytokine immunotherapies involve introducing large amounts of laboratory-

made cytokines to the immune system to promote specific immune responses. Different types include the following:

- Interleukins are cytokines that help regulate the activation of certain immune cells.
- **Interferons** are cytokines that boost the ability of certain immune cells to attack cancer cells.
- Granulocyte-macrophage colony stimulating factor (GM-CSF) is a cytokine that stimulates the bone marrow, promoting the growth of immune and blood cells and the development of dendritic cells.
- Modified bacteria are used to treat certain cancers. Some bacteria have been modified to ensure they will not cause the disease to spread while stimulating an immune response.
- Toll-like receptor agonists "see" patterns in bacteria or viruses and produce a signal that activates the immune cell to attack. The immune system often detects germs through a series of receptors (called toll-like receptors) found on the surface of most immune cells. Several of these specialized receptors have been evaluated for use in cancer treatment.

#### **ONCOLYTIC VIRUS IMMUNOTHERAPY**

One treatment strategy uses viruses to attack cancer. Oncolytic virus immunotherapy involves the use of viruses to directly infect tumor cells and induce an immune response against the infected cells. With one of the most-studied approaches, a modified, weakened version of the herpes simplex virus that also contains the cytokine GM-CSF is used. The virus targets specific cancer cells, infects them and duplicates itself continuously within the cell until it ruptures. This rupture kills the cell and releases the GM-CSF protein induced by the virus to promote an overall immune boost against the cancer. This process increases the chance that the attack can also begin killing cancer cells that have not been infected with the virus.

#### **VACCINATIONS**

Although researchers have been trying to develop vaccines to fight cancer for many years, knowledge gained in recent years is improving this treatment approach. Vaccines against cancer are created from either modified viruses or tumor cells and are designed to direct immune cells to the cancer cells. In some cases, these vaccines are developed from a patient's own tumor, but usually they are "off-the-shelf" and contain

one to more than 100 antigens that are common to the patient's type of cancer. There are two types of cancer vaccines: prophylactic vaccines, which prevent the viruses that cause cancers, and therapeutic vaccines, which treat existing cancers. Currently, prophylactic vaccinations are available for human papillomavirus (HPV), the cause of many cervical, anal, and head and neck cancers, and hepatitis B virus (HBV), a known risk factor for liver cancer.

Therapeutic cancer vaccinations include the following.

- Tumor cell vaccines are made from tumor cells that are similar to a patient's cancer type. (These vaccines are made from a patient's own tumor only in rare cases.) In some cases, the tumor cells are genetically engineered to express a new property or are treated with drugs that make the tumor cells or their components easier for the immune system to recognize. The vaccines are treated with radiation to prevent spreading and are then injected back into the body to help the immune system recognize any remaining cancer cells.
- Antigen vaccines are typically made from one to five of the antigens that are either unique to or overexpressed by tumor cells. They may be specific to a certain type of cancer but are not patient-specific.
- **Dendritic cell** (or antigen-presenting cell [APC]) vaccines are made from white blood cells extracted from the patient. The cells are sent to a lab, exposed to chemicals that turn them into dendritic cells, and then exposed to tumor antigens so that they'll transform into mature APCs. When they're injected back into the patient, they share the antigen information with the T-cells, and any other cells that release that specific antigen are targeted and destroyed.
- Vector-based vaccines are made from altered viruses, bacteria, yeast or other structures that can be used to get antigens into the body. Often, these germs have been altered so that they no longer cause disease. Some vaccines can be used to deliver more than one cancer antigen at a time. Vectorbased vaccines are injected into the body to create an immune response, both specific and overall. Tumor-specific vectors are genetically modified to train the immune system to recognize, target and destroy cancer cells. One vector-based vaccine currently being studied to treat leukemia is an HIV virus (modified to no longer cause disease) that targets B-cells, the cells primarily affected by leukemia. ■

# IMMUNOTHERAPY OFFERS HOPE TO MELANOMA SURVIVOR



One day in July 2008, I noticed a little spot on my right collarbone as I was putting on my makeup. I didn't worry too much about it until it started to change over time and began to look like

a blister. I didn't have a dermatologist, so I found one and had it checked nearly a year later in May 2009.

After testing was done, the doctor looked at the results and said the spot was melanoma in situ. I had surgery to remove the lesion. When the biopsy determined that the margins were not clean, I had a second surgery to remove a lymph node. To follow up, I went to the dermatologist every three months and an oncologist, who did regular chest X-rays.

In September 2014, five years after being free of melanoma, my family and I celebrated that critical milestone. However, on July 4, 2015, I was at a weekend barbeque and suddenly I got a sharp pain under my breast. I called my family doctor and made an appointment for Monday. The doctor did a chest X-ray and looked at my abdomen. Then he ordered a CAT scan and more blood tests.

The results came back, and he told me that I had Stage IV metastatic melanoma that had spread to my liver and ninth rib. The sharp pain in my rib was the only indication I had that something was wrong. I'm glad now that it happened, so I could be diagnosed and start treatment, but at the time, I was completely shocked. I cried for days. I was so scared for my children, even

though they were older, and for my grandchildren. I became depressed and couldn't stop crying, so the doctors put me on an antidepressant, which helped tremendously.

My doctor recommended immunotherapy, which I had never heard of before. I was scared, but when the doctor told me I'd have fewer side effects and wouldn't lose my hair, I felt better. I would have done anything to make the cancer go away. By the end of July 2015, I started receiving infusions of an immunotherapy drug every three weeks. They checked the status of my cancer with computed tomography (CT). As of August 2016, my scans still showed something on my liver and rib, but my doctor told me that they may never fully disappear. With immunotherapy, scar tissue can be left behind, and it can be easily confused with active cancer. The tumor may be "dead," which is what I hope for, but we will continue to monitor it with scans during the rest of my treatment.

I've barely had any side effects with this treatment. It's been amazing. I've not had one sick day or any colds since I started the immunotherapy. The only side effect I had was an itchy, pimply rash, which lasted for about six months. It showed up on my back, arms and chest. The doctor said it was a mild rash and prescribed a corticosteroid cream to help with the itching.

I am glad that I received prompt medical attention after the pain in my ribs, but I did seek other opinions just to be safe. Don't be afraid to get a second or third opinion about your diagnosis. I switched doctors after only two treatments. I found a doctor I felt more confident with, who gave me a stronger sense of hope. It's important to do what feels right for you.

Everyone needs a support group. I didn't tell a lot of people about my melanoma or my treatment. I didn't want to be defined by melanoma. I could not have gone through this without the love and support of my family, especially my children, John and Denise. My two brothers and a sister rounded out my core group of supporters. I never went to a doctor's appointment or treatment without one of my two children. They made sure I was never by myself.

Communicate to those closest to you to let them know what you need. Don't be afraid to ask for what you need. Keep busy and do things if you're feeling up to it. I didn't look sick, so I didn't want to act sick. I just kept going, and that worked for me. Having and treating cancer is only one part of your life.

Look for hope. I had several people add me to their prayer chains, which gave me so much hope. Immunotherapy gave me hope as well. I feel blessed that this treatment is available now.

# PERSONAL JOURNEY | JANE MCNEE

→ Jane McNee, 64, was surprised when her melanoma came back six years after her original diagnosis. This time, it had metastasized to her liver and ninth rib. Her doctor recommended immunotherapy, and the treatment has been successful. The spots on her liver and rib are significantly smaller since treatment began, and she has had only mild side effects. She is enjoying life with her two children and two grandchildren.

# THE ROAD TO IMMUNOTHERAPY

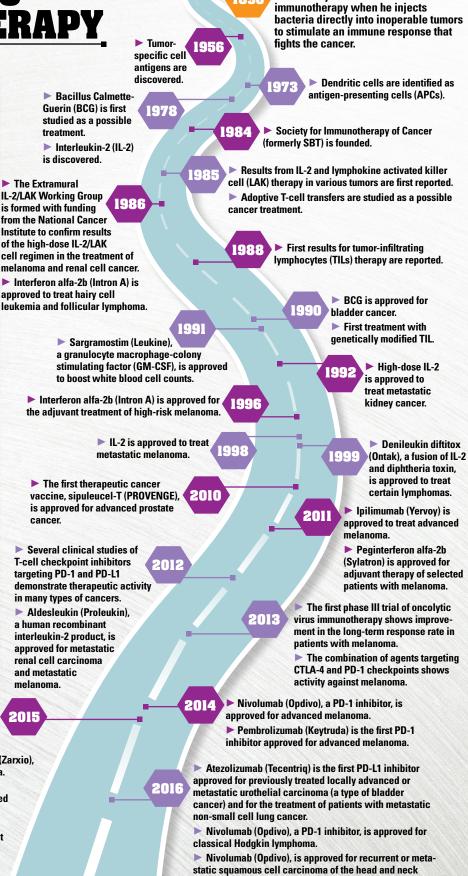
# HISTORY OF IMMUNOTHERAPY

Immunotherapy is a cancer treatment more than 100 years in the making, beginning most notably with Dr. William B. Coley, who worked with patients and other doctors to study how cancer tumors reacted to bacterial infections. He treated people with inoperable tumors by injecting a combination of bacteria, which became known as Coley's Toxins, directly into their tumors. His results showed that this kind of treatment shrank the tumors and sometimes even cured the patient. He believed that the body's increased response to the bacteria also helped fight off

In the modern era, Dr. Donald Morton was an early proponent of immunotherapy, particularly cancer vaccines. His work with bacillus Calmette-Guérin (BCG) for melanoma led to the use — and eventual approval — of BCG for bladder cancer, the first successful immunotherapy against a human tumor.

This timeline describes progress in the development of immunotherapy agents. These agents work by altering the immune system, either by stimulating the production of lymphocytes (a type of white blood cell) or antibodies (special proteins) or by overcoming the ability of cancer cells to "hide" from the immune system and not be recognized as a foreign invader. (Some immunotherapies are monoclonal antibodies, but they should not be confused with monoclonal antibodies that directly attack cancer cells, a type of treatment known as targeted therapy.)

- Elotuzumab (Empliciti), a SLAMF7-directed immunostimulatory antibody, is approved for multiple myeloma.
- ► The first biosimilar product, filgrastim-sndz (Zarxio), is approved to treat severe chronic neutropenia.
- Nivolumab (Opdivo) is the first checkpoint inhibitor approved for lung cancer and advanced renal cell carcinoma.
- ▶ Pembrolizumab (Keytruda) is approved to treat metastatic non-small cell lung cancer that has progressed after other treatments and with tumors that express a protein called PD-L1.
- ➤ Talimogene laherparepvec (Imlygic), a genetically modified oncolytic viral therapy is approved for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma.



with disease progression.

non-small cell lung cancer.

Pembrolizumab (Keytruda) is the first checkpoint

inhibitor approved as a first-line treatment for metastatic

Pembrolizumab (Keytruda) is approved for recurrent or metastatic head and neck squamous cell cancer with

► Dr. Coley creates the first

PatientResource.com disease progression.

# **CANCER TYPES**

#### Immunotherapy as a way to treat

cancer has been studied for more than 100 years. More recently, as doctors have learned from research and clinical trials about how to train the immune system to find and destroy cancer cells, more successes are being reported. Immunotherapy is changing people's lives, offering hope with new treatment strategies. People with cancer are having better outcomes and often enjoying a better quality of life. The future of current and new immunotherapy strategies is promising.

Currently, many types of cancer can be treated with immunotherapy (see FDA-Approved Immunotherapies). Immunotherapy is not approved to treat every subset or every stage of these cancer types, and not every person is able to receive immunotherapy. Talk with your doctor to find out if you meet the criteria required. Because immunotherapy depends on a functioning immune system, it may be important that you not have an autoimmune disorder or are not taking immunosuppressive medications. After considering these and other factors, such as your overall health, type and stage of your cancer and your treatment history, your doctor will determine if you are a candidate for immunotherapy.

#### **ACUTE LYMPHOCYTIC LEUKEMIA**

Acute lymphocytic leukemia (ALL), also referred to as acute lymphoblastic leukemia, is a type of fast-growing cancer of the blood and bone marrow (the spongy tissue inside certain bones that produces blood cells).

Adults with ALL are typically treated in three phases:

- **1. Induction** is designed to kill leukemia cells and put the cancer into remission (absence of disease activity).
- **2. Consolidation,** also referred to as intensification or post-remission therapy, is designed to destroy any leftover, inactive leukemia cells that might regrow and cause a relapse.
- **3. Maintenance** is designed to prevent any new leukemia cells from growing.

Different treatments or combinations of treatments may be used in each phase. Standard treatments for ALL include traditional chemotherapy, immunotherapy, targeted therapy and stem cell transplantation. In special circumstances, radiation therapy and surgery also may be used. In addition, be-

cause standard chemotherapy may not reach the brain and spinal cord, your doctor may treat the leukemia cells in those areas with treatment known as central nervous system prophylaxis. This type of treatment involves drug injections into the cerebrospinal fluid, high-dose chemotherapy or radiation therapy directed at the brain and spinal cord to reach the central nervous system and prevent cancer from spreading there.

In 2014, the U.S. Food and Drug Administration (FDA) approved the first immunotherapy strategy to treat ALL. This type of immunotherapy is indicated for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL. This type of immunotherapy may be used for people who have B-cell ALL that hasn't responded to treatment or B-cell ALL that has come back after treatment.

If neither of those descriptions applies to your specific situation, consider volunteering for a clinical trial. Additional immunotherapy strategies for various types and stages of leukemia are being studied in clinical trials. One particular strategy could open the door to treating early-stage ALL. Adoptive T-cell transfer (ACT) involves modifying the body's own immune cells to recognize and attack tumors. Thus far, ACT research has been limited to small clinical trials for early-stage ALL, but the responses have been positive and research continues through clinical trials.

Clinical trials may give you access to leading-edge treatments that are not yet widely available. Explore the clinical trials currently taking place (see page 16), and ask your doctor for more information.

#### **BLADDER CANCER**

Bladder cancer begins when healthy cells in the bladder lining, most commonly urothelial cells, change and grow uncontrollably, forming a mass called a tumor. A tumor can be cancerous or benign. A cancerous tumor is malignant, meaning it can grow and spread to other parts of the body. A benign tumor means the tumor can grow but will not spread.

Bladder cancer was the first cancer type to receive an approved immunotherapy agent, which was a breakthrough for modern immunotherapy. This agent, bacillus Calmette-Guérin (BCG) was approved by the FDA in 1990 and is now one of the main treatments for nonmuscle-invasive bladder cancer. BCG is a weakened version of the bacterium that causes tuberculosis, and it is delivered directly into the bladder through a catheter. This is

called intravesical therapy (see Figure 1). BCG attaches to the inside lining of the bladder and stimulates the immune system to destroy the tumor. BCG is used for early-stage bladder cancer and as treatment to reduce the risk of recurrence in noninvasive bladder cancers, commonly after surgery to remove the tumors.

Although other treatment options are available for bladder cancer, BCG was the only immunotherapy for bladder cancer until recently. A checkpoint inhibitor, specifically, a PD-L1 inhibitor, is now approved

#### As of 10/26/16

# FDA-APPROVED IMMUNOTHERAPIES

#### **ACUTE LYMPHOCYTIC LEUKEMIA**

blinatumomab (Blincyto)

#### **BLADDER CANCER**

- atezolizumab (Tecentriq)
- bacillus Calmette-Guérin (BCG)

#### CHRONIC LYMPHOCYTIC LEUKEMIA

- alemtuzumab (Campath)
- obinutuzumab (Gazyva)
- ofatumumab (Arzerra)
- rituximab (Rituxan)

#### **FOLLICULAR LYMPHOMA**

- ibritumomab tiuxetan (Zevalin)
- interferon alfa-2b (Intron A)
- obinutuzumab (Gazyva)

#### **HAIRY CELL LEUKEMIA**

interferon alfa-2b (Intron-A)

# HEAD AND NECK CANCER

- nivolumab (Opdivo)
- pembrolizumab (Keytruda)

#### **HODGKIN LYMPHOMA**

nivolumab (Opdivo)

#### **KIDNEY (RENAL) CANCER**

- interleukin-2 (Proleukin)
- nivolumab (Opdivo)

#### LUNG CANCER

- atezolizumab (Tecentriq)
- nivolumab (Opdivo)
- pembrolizumab (Keytruda)

### **MANTLE CELL LYMPHOMA**

lenalidomide (Revlimid)

#### **MELANOMA**

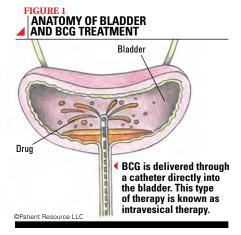
- high-dose interleukin-2 (IL-2)
- interferon alfa-2b (Intron A)
- interleukin-2 (Proleukin)
- ipilimumab (Yervoy)
- nivolumab (Opdivo)
- peginterferon alfa-2b (Sylatron)
- pegylated interferon alfa-2b (PEG-Intron)
- pembrolizumab (Keytruda)
- talimogene laherparepvec (Imlygic)

#### **MULTIPLE MYELOMA**

- daratumumab (Darzalex)
- elotuzumab (Empliciti)
- lenalidomide (Revlimid)
- pomalidomide (Pomalyst)
- thalidomide (Thalomid)

#### **NON-HODGKIN LYMPHOMA**

rituximab (Rituxan)



for locally advanced or metastatic urothelial carcinoma, the most common form of bladder cancer, in people in whom disease progressed during or following chemotherapy containing a platinum drug or in whom disease progressed within 12 months after neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Although other advancements have been slow for this disease, research is ongoing to develop treatments, including immunotherapies, for bladder cancer. Several drugs are in clinical trials, and immunotherapy continues to show promise for additional bladder cancer treatment options in the near future. One strategy being explored through clinical trials is combinations of immunotherapies. Future research could open the door to more treatment options involving immunotherapy, which could offer new hope to people who have bladder cancer.

Be sure to talk with your doctor about which treatment options are best for you, especially since not all immunotherapies are approved for all types and stages of bladder cancer.

#### CHRONIC LYMPHOCYTIC LEUKEMIA

Chronic lymphocytic leukemia (CLL) is a blood and bone marrow disease that usually gets worse slowly. CLL is one of the most common types of leukemia in adults. Normally, the body makes blood stem cells (immature cells) that become mature blood cells over time. A blood stem cell may become a myeloid stem cell or a lymphoid stem cell. In CLL, too many blood stem cells become abnormal lymphocytes (a type of white blood cell) and do not become healthy white blood cells. The abnormal lymphocytes also may be called leukemia cells. The lymphocytes are not able to fight infection very well. As the number of lymphocytes increases in the blood and bone marrow (soft, spongy center of bone), there

is less room for healthy white blood cells, red blood cells and platelets. This may cause infection, anemia and easy bleeding.

Treatment options for CLL include watchful waiting, chemotherapy, targeted therapies, immunotherapies, stem cell transplantation, radiation therapy and surgery. Many first-line treatments are currently available for CLL. The choice of treatment will depend on the stage of the disease and whether the patient has symptoms, age, overall health and the benefits versus side effects of treatment. Immunotherapy drugs for CLL first became available in 2007 with a monoclonal antibody that targets an antigen (protein) known as CD52, which is a common antigen found on B and T-cells (cells in the body's immune system). Several additional monoclonal antibodies that target CD20 have since been approved for CLL.

Many treatments are currently being tested in clinical trials for people with both newly diagnosed and relapsed/refractory CLL. The combination of chemotherapy and immunotherapy (chemoimmunotherapy) is being explored as induction therapy in patients with newly diagnosed CLL. Researchers are also investigating ways to improve stem cell transplantation in patients with CLL. Genetically engineered immune cells, or T-cells, designed to recognize and kill CLL cells are another area of research for treating CLL.

Today's scientific research is continuously evolving, and treatment options may change as new treatments are discovered and current treatments are improved. Clinical trials are testing new options, and one may be right for you. Ask your doctor if you are a candidate for clinical trials before deciding on any treatment options. Clinical trials may give you access to some of the most leading-edge therapies available.

#### **FOLLICULAR LYMPHOMA**

Lymphoma occurs when cells of the immune system called lymphocytes, a type of white blood cell, grow and multiply uncontrollably. These cancerous lymphocytes can travel to many parts of the body and form a mass called a tumor. Two main types of lymphocytes develop into lymphomas: B lymphocytes (B-cells) and T lymphocytes (T-cells). Follicular lymphoma is a B-cell lymphoma and is the most common indolent (slow-growing) form of non-Hodgkin lymphoma (NHL).

Follicular lymphoma usually begins in the lymph nodes and can spread into the blood and bone marrow (soft, spongy tissue in the center of some bones) or other organs. For Stage I and early Stage II follicular lymphoma, radiation therapy is often recommended to target the lymph nodes affected by the lymphoma and the surrounding area. Other treatment options include immunotherapy, chemotherapy or both.

Follicular lymphoma grows slowly, so your doctors may recommend "watchful waiting" instead of beginning treatment right away if you are otherwise healthy and the lymphoma is not causing any symptoms or problems with other organs.

Immunotherapy combined with chemotherapy is the most common treatment for more advanced Stage II, Stage III and Stage IV disease. One of the first immunotherapies approved for follicular lymphoma was a type of interferon, which is a cytokine. Cytokines act primarily by communicating between the various cells of the body's immune system. It is classified as a biologic response modifier (BRM). Immunotherapy drugs may be used alone if chemotherapy cannot be tolerated. Additionally, if some lymph nodes are very large from the lymphoma, radiation therapy may be used to reduce symptoms.

If follicular lymphoma does not respond to treatment or returns after treatment, your doctor may recommend other types or combinations of immunotherapy, chemotherapy, targeted therapy or stem cell transplantation. These therapies may be FDA-approved or part of a clinical trial.

Current follicular lymphoma clinical trials are designed to investigate treatment strategies to increase the remission rate or cure the disease. Results from clinical trials of Stage III disease show promise for a personalized vaccine to treat follicular lymphoma; the patient's own cancer cells are mixed with immune cells as well as agents to stimulate the immune system. The immune cells learn to recognize the cancer cells as foreign and are then used in the vaccine together with an agent that stimulates the immune system. Once the vaccine is given, the immune cells recognize and fight cancer cells that may be in the body. Ask your doctor if you are a candidate for clinical trials.

#### HAIRY CELL LEUKEMIA

Hairy cell leukemia is a rare type of leukemia that is a cancer of the blood and bone marrow, which is the soft tissue in the center of most bones. It gets its name from the "hairy" appearance its cells have when viewed under a microscope. In hairy cell leukemia, too many blood stem cells become lymphocytes, which are white blood cells that help fight infections.

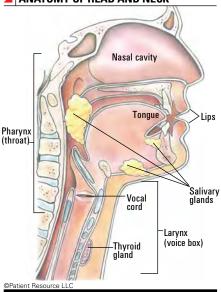
However, these lymphocytes are abnormal and do not become healthy white blood cells. They also are called leukemia cells. The leukemia cells can build up in the blood and bone marrow so there is less room for healthy white blood cells, red blood cells and platelets. This may cause infection, anemia and easy bleeding. Some of the leukemia cells may collect in the spleen and cause it to swell.

Standard treatment options for hairy cell leukemia include watchful waiting, chemotherapy, surgery, targeted therapy and immunotherapy. One type of immunotherapy has been approved for hairy cell leukemia. It is considered a biologic response modifier (BRM), which stimulates the immune system to indirectly affect tumors. For hairy cell leukemia, the approved BRM is a cytokine, which is a protein that enables cells to send messages to each other. Typically the cytokines used for hairy cell leukemia are interferons.

Alpha interferon was approved in 1986 and represented a new and exciting advance in the treatment of hairy cell leukemia. Until that time, splenectomy, or the removal of the spleen, was the only known effective therapy for this disease. Interferon benefited people with active hairy cell leukemia, regardless of whether they had a splenectomy. At the present time, interferon has a relatively limited role in the treatment of hairy cell leukemia, so discuss with your doctor if it is appropriate for you.

New types of treatment are being tested in clinical trials. Although immunotherapy is not a first-line therapy for hairy cell leukemia, clinical trial research is investigating immunoconjugates, *BRAF* inhibitors and B-

A | ANATOMY OF HEAD AND NECK



cell receptor inhibitors. These options have shown some benefits in people with hairy cell leukemia, but they've been studied only for hairy cell leukemia that has come back after or not responded to treatment and only in a small number of people. Clinical trials offer people the opportunity to try these therapies that may be very beneficial for their type and stage of cancer. Talk to your doctor about all of your treatment options and ask if a clinical trial may be the best option for you.

#### **HEAD AND NECK CANCER**

Head and neck cancer describes a variety of malignant (cancerous) tumors that affect the mouth, pharynx (throat), larynx (voice box), sinuses, nose, thyroid and salivary glands (see Figure 2). Most of these cancers begin in the squamous cells that make up the moist tissues lining the nose, mouth and throat; others form in the cells of the thyroid and salivary glands.

The areas affected by head and neck cancer treatment control vital functions, including breathing, swallowing, chewing and speaking. As a result, treating head and neck cancer is more than removing a tumor and killing cancer cells. It also includes repairing the body so that patients can still perform those functions.

The main treatment options for head and neck cancers have included surgery, radiation therapy, chemotherapy and targeted therapy. Surgery or radiation therapy alone or in combination may be part of a person's treatment plan. In 2016, the FDA approved the first immunotherapy drugs for head and neck cancer, specifically for recurrent or metastatic head and neck squamous cell carcinoma that progressed during or after chemotherapy that contained a platinum drug. These immunotherapy drugs are checkpoint inhibitors (see page 4) that target the PD-1 protein on certain immune cells (T-cells).

Immunotherapy offers people with this type of head and neck cancer an alternative treatment option that is less invasive and disfiguring than some surgeries, bringing new hope to people with cancers in this area of the body.

Research continues to expand in developing new treatment options for head and neck cancers. Clinical trials are investigating the use of the current FDA-approved immunotherapy to treat early-stage head and neck cancers and to find other types of immunotherapies that boost the immune system in different ways. Immunotherapies approved for other types of cancers are being evaluated for head and neck cancers.

Clinical trials for immunotherapies are expanding, and you may qualify to participate. As a result, you may have access to some of the newest immunotherapy options. Talk with your doctor to determine if a clinical trial is right for you. Your doctor will discuss with you the best treatment options available to you for your type and stage of head and neck cancer.

#### HODGKIN LYMPHOMA

Hodgkin lymphoma (HL) is a cancer that starts in the part of the body's immune system known as the lymphatic system. The lymphatic system is composed of lymphoid tissue, lymph and lymphatic vessels. Lymphoid tissue, made up primarily of white blood cells called lymphocytes, is found in many parts of the body, including the lymph nodes, spleen, bone marrow (soft, spongy tissue in the center of most bones), thymus, adenoids and tonsils, and digestive tract.

The two main classifications of this type of lymphoma are classic HL and nodular lymphocyte-predominant Hodgkin lymphoma (NLPHL). Classic HL accounts for most Hodgkin lymphoma cases.

The cure rate for HL is generally high. Standard treatment is chemotherapy or radiation therapy, or a combination of both. Although advances in both the diagnosis and treatment of HL have helped contribute to a high cure rate, researchers have continued to look for additional options for people who have hard-to-treat HL. Until recently, if the disease progressed, returned after treatment or stopped responding to treatment, the primary option was high doses of chemotherapy followed by stem cell transplantation and additional drug therapy. Surgery also may be considered under special circumstances but is used primarily to obtain a biopsy for diagnostic purposes.

Today, people with hard-to-treat HL have a new treatment option in immunotherapy.

In September 2016, the FDA approved an immunotherapy drug for classic HL that has returned or progressed after a specific type of stem cell transplantation and post-transplantation medicine.

This particular type of immunotherapy is a monoclonal antibody that inhibits a protein receptor called PD-1 on T-cells, a type of immune cell. PD-1 belongs to a family of so-called checkpoint inhibitors that, when activated, "put the brakes on" the immune system. As a result, this type of immunotherapy prevents tumor cells from communicating through the PD-1 protein to inactivate T-cells, allowing the immune system to attack

the tumor cells. Clinical studies for HL have shown that this checkpoint inhibitor is effective at shrinking the tumors.

This treatment option brings with it new hope for people with relapsed HL. Researchers are using clinical trials to continue exploring the use of this immunotherapy drug in combination with other therapies, as well as new drugs, to treat all stages of HL. Before making any treatment decisions, ask your doctor if this new immunotherapy drug is right for you or if you may be a candidate for a clinical trial.

#### **KIDNEY (RENAL) CANCER**

Cancer that develops in the kidneys is called kidney cancer (or renal cell carcinoma). The most common type of kidney cancer affects the lining of the tubules (very small tubes) inside the kidneys. This type of cancer is called renal cell carcinoma (RCC), and it accounts for 90 percent of all kidney cancers (see Figure 3).

Treatment options for kidney cancer include surgery, targeted therapy or immunotherapy, used alone or together. Radiation therapy and chemotherapy are occasionally used. Surgery is often the primary treatment for most kidney cancers. Because kidney cancer is usually resistant to chemotherapy and radiation therapy, targeted therapy is typically the first line of treatment for advanced kidney cancer. This means the development of additional targeted therapies and immunotherapies is extremely important in the fight against this disease.

Kidney cancer has several immunotherapies available for treatment. One type is a laboratory-made cytokine which can be used to shrink tumors and reduce the risk of recurrence. Cytokines are proteins that enable cells to send messages to each other. Another immunotherapy is a monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2. These FDA-approved drugs are used commonly and work by functioning as immune system messengers designed to elicit a desired response, such as preventing cancer cell growth or making the cancer cells more susceptible to an attack.

Immunotherapy offers hope for people with kidney cancer, but the currently approved immunotherapy drugs are not approved for treating all stages of the disease. So, talk with your doctor to see if these drugs are an option for your type and stage of kidney cancer.

Researchers have tested multiple combinations of the approved cytokines for advanced kidney cancer, and these treatments also have been combined with chemotherapy. Researchers are working to learn more about how the drugs destroy kidney cancer cells and which patients can benefit the most from these treatments. Newer forms of immunotherapy, called checkpoint inhibitors, also are being tested in clinical trials.

Clinical trials may offer you a chance to receive access to the newest medications and may help if current treatments are not working as effectively as expected, or if you have a particularly rare form of kidney cancer. Talk with your doctor to decide if an immunotherapy clinical trial is right for you. Discuss all of the treatment options available to you for your type and stage of kidney cancer with your doctor before making treatment decisions.

#### **LUNG CANCER**

Lung cancer is cancer that starts in the lungs, often in the epithelial cells, which are the cells that line the airways. If left untreated, the primary tumor in the lung can grow and invade

ANATOMY OF LUNGS AND POSSIBLE METASTASES

AND POSSIBLE METASTASES

Stage IV

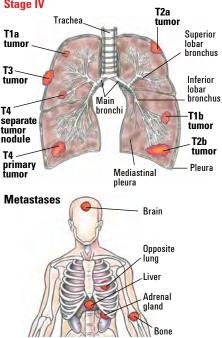
Trachea

The tumor

Trachea

The tumor

Trachea



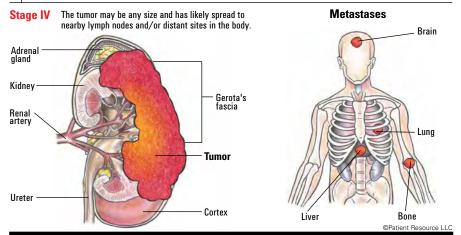
the tissue surrounding the lung. The cancer cells can replace so many normal cells that it becomes difficult for the person to breathe. Sometimes cancer cells break off from the primary tumor and form secondary tumors in nearby sites, such as another lobe of the lung, or distant sites, such as the brain. This spread of cancer is called metastasis. When metastasis occurs, the cancer found in the new region is still considered lung cancer and is treated as such. For example, lung cancer that has spread to the liver is still considered lung cancer, not liver cancer (see Figure 4).

Several options are available to treat lung cancer, including surgery, chemotherapy, radiation therapy, targeted therapy and immunotherapy. When possible, surgery is the primary treatment to remove tumors that are caught early. Other types of treatment often depend on the specific type of lung cancer and a person's overall health.

Using immunotherapy to treat lung cancer is a relatively new option, but now checkpoint inhibitors are an effective strategy for treatment. These checkpoint inhibitors work by stopping the action of a protein, PD-L1, which can prevent your immune system from attacking lung cancer cells. In addition to checkpoint inhibitors, other types of immunotherapy strategies are currently being studied in clinical trials.

This promising treatment is changing the course of lung cancer treatment. Some people with metastatic lung cancer are living

# FIGURE 3 ▲ | ANATOMY OF THE KIDNEY AND POSSIBLE METASTASES



longer with a better quality of life, due in part to fewer and more manageable side effects.

Your treatment plan may include a combination of several treatments or a clinical trial. Your doctor will create a specific treatment plan for your diagnosis depending on several factors, including the type and stage of your lung cancer, the location of the tumor, results of biomarker testing, your overall lung function and your general health. When discussing treatment options with your doctor, make sure you know the type of lung cancer you have, including any information about biomarkers specific to your tumor. Understanding as much as you can about your cancer will help you make more informed treatment decisions.

#### MANTLE CELL LYMPHOMA

Lymphoma is the name for a group of cancers that arise from a type of white blood cell called a lymphocyte. Lymphomas are divided into Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL). Mantle cell lymphoma (MCL) is one of about 70 different subtypes of NHL. MCL results from a malignant transformation of a B lymphocyte (B-cell) in the outer edge of a lymph node follicle. The transformed B-cell grows in an uncontrolled way, resulting in the accumulation of lymphoma cells, which causes enlargement of lymph nodes. Sometimes, when these lymph nodes become very large, or grow in other parts of the body, they can be called tumors. The MCL cells can enter the lymphatic channels and the blood and can spread to other lymph nodes or tissues, such as the bone marrow, liver and gastrointestinal tract.

Treatment options for MCL include watchful waiting, chemotherapy, targeted therapy, stem cell transplantation and immunotherapy. Although chemotherapy is the most commonly used treatment for MCL, in 2013, the FDA approved an immunotherapy drug for treating MCL. This drug is typically combined with a chemotherapy drug.

The immunotherapy drug is only approved for MCL in people who have disease that relapsed or progressed after two prior therapies. For this group of people, the use of immunotherapy with chemotherapy has lead to better results than the use of immunotherapy alone. As a result, this is offering hope to people with MCL as an additional treatment option.

Multiple classes of therapies and drugs are under investigation for MCL. You may want to ask your doctor about participating in a clinical trial because new therapies are constantly emerging. Participating in a clinical trial may offer you the best chance of receiving the most leading-edge treatments available. Some of the immunotherapies being studied in clinical trials include immunomodulators, which are substances that regulate the function of the immune system and can slow the rate at which cancer cells grow and multiply, and radioimmunotherapy, which combines the cancer-killing ability of radiation therapy with the targeting capability of immunotherapy to deliver lethal doses of radiation directly to cancer cells.

Before deciding to participate in a clinical trial, talk with your doctor to discuss all of the options available and which are the best fit for your stage and type of MCL.

#### **MELANOMA**

Skin cancer that becomes malignant (cancerous) is called melanoma. It begins in melanocytes, which are cells that produce melanin, the substance that colors the skin, hair and eyes. Although melanoma is primarily a cancer of the skin, it can affect other parts of the body, including the eyes, mouth, genitals and anal area. Melanoma is the most dangerous type of skin cancer because it's likely to spread to other parts of the body if it is not caught early.

The standard therapies for melanoma include surgery, chemotherapy, radiation ther-

apy and immunotherapy. Surgery remains the main treatment for Stages I through III, and as a palliative (support) treatment to relieve symptoms of advanced disease. Of all the cancers immunotherapies have been tested on, melanoma is one of the most responsive cancers to such treatment, which is bringing new hope to people with the disease. For many people with melanoma, immunotherapy is successful in terms of shrinking tumors, reducing the risk of the cancer coming back, and leading to longer life.

Multiple immunotherapies have been approved by the FDA for melanoma, including several new immunotherapy drugs for advanced melanoma. These new therapies have resulted in significant advancements in the evolution of immunotherapy for melanoma and the treatment of melanoma in general.

The first immunotherapy drug for melanoma was a cytokine that was approved for treatment after surgery for patients at high risk of the cancer recurring. Today, immunotherapy also is used to treat some metastatic melanomas, either alone or in combination with other treatments. Additional immunotherapies have been approved over the years, making melanoma one of the few cancer types for which a variety of immunotherapies have been approved including cytokines, monoclonal antibodies, oncolytic virus therapy and checkpoint inhibitors.

Multiple clinical trials are taking place to investigate new immunotherapies and combinations of currently approved immunotherapies. Because melanoma has been so responsive to new immunotherapies, researchers are investigating, through clinical trials, whether some immunotherapies approved for advanced or metastatic melanomas could be used for earlier stage melanomas.

Currently, immunotherapy is a significant focus in cancer research and drug development, especially with melanoma. As newer cancer treatments are discovered, they first

#### > ADDITIONAL RESOURCES

#### **ACUTE LYMPHOCYTIC LEUKEMIA**

**American Cancer Society:** www.cancer.org Acute Lymphocytic Leukemia

Leukemia & Lymphoma Society: www.lls.org

Disease Information

#### **BLADDER CANCER**

American Bladder Cancer Society: www.bladdercancersupport.org

**Bladder Cancer Advocacy Network:** www.bcan.org

**United Ostomy Associations of** America Inc.: www.ostomy.org

#### CHRONIC LYMPHOCYTIC LEUKEMIA

Leukemia and Lymphoma Society: www.lls.org

**Cancer Research Institute:** 

www.cancerresearch.org

#### **FOLLICULAR LYMPHOMA**

NHL Staging

Leukemia & Lymphoma Society: www.lls.org Clinical Trials

Lymphoma Information Network: www.lymphomainfo.net Follicular Lymphoma

#### Lymphoma Research Foundation:

www.lymphoma.org Follicular Lymphoma

#### HAIRY CELL LEUKEMIA

Hairy Cell Leukemia Foundation: www.hairycellleukemia.org

Leukemia and Lymphoma Society: www.lls.org Hairy Cell Leukemia

#### **HEAD AND NECK CANCER**

**American Cancer Society:** www.cancer.org If You Have Head or Neck Cancer

#### **HNC Living Foundation:**

www.hncliving.org Resources

# **National Cancer Institute:**

www.cancer.gov Head and Neck Cancers

#### HODGKIN LYMPHOMA

**American Cancer Society:** www.cancer.org What Is Hodgkin Disease?

### **National Cancer Institute:**

www.cancer.gov Adult Hodgkin Lymphoma Treatment—Patient Version

become available in clinical trials for those who are eligible. Talk to your doctor to see whether a clinical trial is right for you and to discuss all of the treatment options available for your type and stage of melanoma.

#### MULTIPLE MYELOMA

Multiple myeloma falls into the general category of hematologic (blood) cancers, which primarily affect the blood, bone marrow (soft, spongy center of most bones) and lymph nodes, changing the production of blood cells and the way that they work. Myeloma affects the plasma cells found inside the bone marrow where blood is made. Myeloma cells develop when normal plasma cells transform and grow uncontrollably (see Figure 5). As these abnormal cells multiply, they suppress the growth of healthy cells in the bone marrow. Because plasma cells are a part of the body's immune system, this unusual cell growth can affect the body's ability to fight infection and can result in anemia, bone damage and excessive bleeding from cuts.

Multiple myeloma is the second most common form of blood cancer in the United States. Thus, improved ways to treat this type of cancer is needed. Immunotherapies are a promising new strategy to treat multiple myeloma.

Treatment usually includes a combination of therapies, except for surgery, which is not typically part of routine treatment for this cancer. For many years, standard treatments for symptomatic myeloma have included chemotherapy, stem cell transplantation, and, in some cases, radiation therapy. Now immunotherapies are also an option. These therapies include a monoclonal antibody that is directed against CD38, a molecule that is present on myeloma cells, and other immunomodulatory agents, which stimulate the immune system. These immunotherapies can be used only for people who have received previous treatments or in combination with other drugs. They are

not approved for all types and stages of multiple myeloma.

A new, promising aim of clinical research in multiple myeloma is the use of immune checkpoint inhibitors. These treatments work by targeting molecules that serve as checks and balances in the regulation of immune responses. By blocking inhibitory molecules or, alternatively, activating stimulatory molecules, these treatments are designed to unleash or enhance pre-existing anticancer immune responses. Other immunotherapies in clinical trials for multiple myeloma include vaccines, cytokines, adoptive cell transfer, monoclonal antibodies and oncolytic virus therapies.

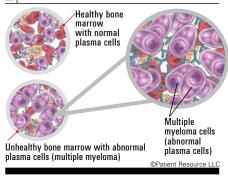
As new cancer treatments are discovered for multiple cancer types, including multiple myeloma, they first become available in clinical trials for those who are eligible. Talk to your doctor to see whether a clinical trial is right for you and to discuss all of the treatment options available for your type and stage of multiple myeloma.

#### **NON-HODGKIN LYMPHOMA**

Non-Hodgkin lymphoma (NHL), a type of cancer that forms in the lymphatic system (a network of vessels through which lymph is carried), is not a single disease but a group of several closely-related cancers. In NHL, B-cells, T-cells or natural killer (NK) cells in the lymphatic system change and grow uncontrollably, sometimes forming a tumor. The most common type of NHL is B-cell lymphoma. T-cell lymphoma is less common, and NK-cell lymphoma is relatively rare. NHL can start almost anywhere and can spread to almost any organ. It most often begins in the lymph nodes, liver, spleen or bone marrow, but it can also involve the stomach, intestines, skin, thyroid, brain or any other part of the body where lymphatic tissue is found.

Treatment options for NHL include chemotherapy, immunotherapy, targeted

FIGURE 5
| ANATOMY OF BLOOD CELLS
| AND MYELOMA CELLS



therapy, radiation therapy and stem cell transplantation. The treatment options used depend on the type of lymphoma and its stage (extent), as well as other prognostic factors. Standard options are often tailored to the particular situation for an individual patient. Radiation therapy is used less frequently than the other options, and surgery is used in rare cases. NHL is usually treated with a monoclonal antibody drug combined with chemotherapy.

The first successful immunotherapy introduced for lymphoma is a monoclonal antibody that targets a special protein (CD20) on NHL cells. This immunotherapy drug is now regularly available for all B-cell lymphomas.

Many clinical trials are evaluating possible immunotherapy drugs or combinations. Researchers have been focused on checkpoint inhibitors such as PD-1, PD-L1 and CTLA-4 antibodies, alone, and in combination. Other antibodies also are being tested in trials. Adoptive cell therapy is another type of immunotherapy being tested in clinical trials. One specific form of this approach is called chimeric antigen receptor (CAR) T-cell therapy. Multiple vaccines also are in clinical trials for NHL.

Talk with your doctor about treatment options that are right for you and your stage of cancer. Many clinical trials are evaluating immunotherapies for NHL. Discuss these trials as a treatment option with your doctor. ■

#### KIDNEY CANCER

**Action to Cure Kidney Cancer:** www.ackc.org

American Cancer Society: www.cancer.org Kidney Cancer

**Kidney Cancer Association:** www.kidneycancer.org

National Kidney Foundation: www.kidney.org

#### LUNG CANCER

American Society of Clinical Oncology: www.cancer.net Lung Cancer — Non-Small Cell: Diagnosis

#### International Association for the Study of Lung Cancer:

www.iaslc.org About Lung Cancer

#### LUNGevity:

www.lungevity.org About Lung Cancer

#### MANTLE CELL LYMPHOMA

**Leukemia and Lymphoma Society:** www.lls.org *Types of non-Hodgkin Lymphoma* 

**Lymphoma Research Foundation:** www.lymphoma.org

#### MELANOMA

American Melanoma Foundation: www.melanomafoundation.org

**Melanoma International Foundation:** www.melanomainternational.org

Melanoma Research Foundation: www.melanoma.org

#### MULTIPLE MYELOMA

**International Myeloma Foundation:** www.myeloma.org

Myeloma Central: www.myelomacentral.com The Multiple Myeloma Research Foundation: www.themmrf.org

#### NON-HODGKIN LYMPHOMA

#### **American Cancer Society:**

www.cancer.org Non-Hodgkin Lymphoma

American Society of Clinical Oncology: www.cancer.net Lymphoma – non-Hodgkin: Subtypes

**Leukemia and Lymphoma Society:** www.lls.org *Non-Hodgkin Lymphoma* 

# SIDE EFFECTS

Although using immunotherapy typically results in fewer side effects that can be less severe than those associated with other forms of cancer treatment, some side effects still can occur, and some may be serious. Not everyone will experience the same side effects with immunotherapy, and some people may not experience any at all. Symptoms can vary in severity and differ according to the type of immunotherapy.

Some common side effects associated with immunotherapy are discussed here.

- Immune-mediated adverse reactions are not common but can occur with certain immunotherapies. This type of reaction occurs when the immune system is overstimulated by the treatment and may cause inflammation, swelling or redness, which may be painful. Following are some of the systems affected by immune-mediated adverse reactions and common symptoms:
- Endocrine (endocrinopathies): hyperthyroidism, hypothyroidism, extreme fatigue, persistent or unusual headaches
- Gastrointestinal (colitis): diarrhea with or without bleeding, abdominal pain, bowel perforation
- Neurologic (neuropathies): numbness or tingling, sensory overload or sensory deprivation
- Pulmonary (pneumonitis): chest pain, shortness of breath
- Renal (kidneys) (nephritis): Decrease in urine output, blood in urine, swelling in ankles, loss of appetite

• Skin (dermatitis): Rash, skin changes

Since immunotherapy works differently than other cancer treatments, partnering with your doctor to monitor for complications is vital. To determine what is normal for you, your doctor likely will perform baseline assessments for monitoring purposes throughout treatment. You will play a key role in detecting what is abnormal for you and communicating that to your doctor immediately, so it is important to understand how to recognize an immune-mediated adverse reaction, as some may not produce obvious symptoms.

Having the appropriate contact information handy is important. Before beginning immunotherapy, ask your health care team whom to call, day or night, if you think you may be having an immune-adverse mediated reaction. It is necessary to call that person immediately to avoid any life-threatening complications. Without treatment, an autoimmune response can be irreversible or even deadly. For the majority of reactions, early intervention can be reversed with steroids and by temporarily stopping immunotherapy.

These types of side effects can be delayed, sometimes occurring weeks or even months after treatment stops. Work with your doctor to determine a plan for how long to be vigilant about potential side effect symptoms.

**Fatigue** is the most common side effect reported in multiple immunotherapies, including checkpoint inhibitors, cytokines and oncolytic virus therapy. Fatigue associated with cancer is different than simply feeling tired and may cause you to feel physically, emotionally or mentally exhausted.

- Flu-like symptoms, such as fever, chills, aches, headache, drowsiness, nausea, vomiting and loss of appetite, can occur with cytokines or oncolytic virus therapy.
- Diarrhea is common with checkpoint inhibitors and can vary in severity and duration. Diarrhea can lead to severe dehydration and electrolyte imbalance, but also could be a symptom that your immune system is going into overdrive. Call your health care team if you experience symptoms that interfere with your daily activities, such as severe abdominal cramping, or that cause you to fear leaving your home.
- Mild skin reactions, such as bumpy or itchy red rashes, can occur. These reactions can be common with checkpoint inhibitors. Other skin problems include yellowing or changes in skin color, blistering, hives, pale patches and flushing or redness. Although rarely severe, these symptoms can be uncomfortable. Your doctor may recommend a corticosteroid or numbing medicine, an antihistamine, medicated creams or antibiotics.
- **Depression** can affect your mood, behavior and ability to think and concentrate, as well as be associated with fatigue, appetite loss, difficulty falling asleep or extreme tiredness. Depression can include suicidal thoughts or other psychiatric disorders. Call your doctor's office if you notice these types of mood changes.

Frequent communication with your health care team is important for monitoring your symptoms. Seek treatment immediately, regardless of time of day, for any medical emergencies, including high fever, inflammation, swelling, severe abdominal pain or shortness of breath. ■



# **GLOSSARY**

#### QUICK REFERENCE GUIDE

# The Immune System and Immunotherapy

**Antibody** — A protein created by B-cells in direct response to specific antigens. An antibody attaches itself to its respective antigen, marking it for other immune cells to "see" and destroy.

Antigen — A protein produced by a cell, virus or bacteria. In the case of cancer antigens, the protein or part of a protein is on the surface of the cancer cell. It alerts the immune system and causes the production of antibodies or the creation of T-cells that can recognize and potentially destroy the cancer cells expressing that antigen.

**Antigen-presenting cells (APCs)** – Special cells that digest invading cells or soluble (can be dissolved in water) protein antigens and present them to the T-cells and B-cells so they know what to attack.

**B-cells** – Immune cells that produce antibodies for specific antigens that will bind to the antigens and mark them for destruction by other immune cells.

**Biologic product** – Medications made from living organisms, such as vaccines, human cells and tissues, and gene therapies.

**Biosimilar** – A product approved as an alternative to an FDA-approved biologic product based on its similarities and meeting standards for interchangeability, with no clinically meaningful differences between the two. The first FDA-approved biosimilar is filgrastim-sndz (Zarxio), approved in 2015.

Cancer cells — Cells with damaged DNA that causes mutations in normal cell growth and division. New cancer cells grow uncontrollably and old cancer cells don't die when they should, resulting in a malignant tumor or cancer

**Co-stimulatory signal** – The second stimulation required for T-cells to become fully activated (also called Signal 2).

CTLA-4 (cytotoxic T lymphocyte associated antigen 4) — A protein receptor found on the surface of T-cells. This protein is part of the CTLA-4 checkpoint pathway, which can shut down an immune system response in its early stages. Certain cancer cells have the ability to turn on this checkpoint, which stops the immune response against the cancer cells.

**Cytokines** – Proteins released by immune cells to communicate with other immune cells. Certain cytokines, such as interferon and interleukin, help regulate specific immune system functions.

**Dendritic cell (DC)** – A type of antigen-presenting cell responsible for processing antigen material and presenting it to the T-cells and B-cells for activation. DCs also are able to help regulate other immune cells.

**Downregulation** – Reducing either the overall immune system response or the specific responses of certain immune cells.

**Granulocyte-macrophage colony stimulating factor (GM-CSF)** – A protein responsible for stimulating bone marrow and promoting the growth of immune

cells, especially dendritic cells. GM-CSF is currently used to restore white blood cells that have been depleted in people receiving chemotherapy and is being used and studied as a treatment boost when combined with other immunotherapies.

Immune cells – The cells of the immune system involved in defending the body against infectious disease, foreign invaders and cancer cells.

Immune checkpoint inhibitors — Drugs that block the activation of specific immune checkpoint pathways. These drugs allow the immune system to 'take the brakes off,' which allows the immune system to recognize and attack cancer cells.

Immune checkpoint pathways — The system of checks and balances in place to prevent overactivation of the immune system. Different pathways function at different stages of the immune response to help regulate the length and intensity of T-cell activity; turning on an immune checkpoint typically results in shutting down the immune system response.

Immunosuppression — A condition in which the immune system is prevented from launching successful attacks to protect the body against infection and disease.

**Immunotherapy** – A type of cancer treatment that focuses on using the body's own immune system to fight cancer.

Immune-related adverse events (IRAEs) — Autoimmune reactions that occur as a result of boosting the immune system. Severe reactions may include colitis, dermatitis and hepatitis.

Interferon — A protein released by immune cells that helps regulate different immune cell activity; types of interferon include alpha, beta, gamma and lambda. Different types help regulate different functions, including prompting increased T-cell activity, stimulating natural killer cells or affecting certain cell functions that influence tumor cell growth. Laboratory-made versions of the IFN-alpha protein are currently FDA-approved to treat certain types of cancer.

Interleukin – A protein produced by cells of the immune system that helps regulate the production of certain immune cells, how they function during an immune response and their production of cytokines. The laboratory-made version of this protein, aldesleukin (Proleukin), is currently FDA-approved to treat metastatic melanoma and metastatic renal cell carcinoma (kidney cancer).

**Ligands** – Protein molecules on the surface of a cell that bind to the receptor on the surface of another cell. Most ligands are signal-triggering molecules, which means they send out immune cell signals when engaged by a receptor. These signals help to regulate specific immune system functions.

Major histocompatibility complex (MHC) — A set of proteins on the surface of certain immune cells that influence the interaction of normal cells with immune cells. Antigen-presenting cells present digested antigens to T-cells through the MHC on their surface, which allows the T-cells to "see" the antigen and recognize it as foreign. The connection between the MHC and the receptor on the T-cell is the first signal (Signal 1) necessary to activate the T-cell to respond to a tumor and destroy it.

Memory cells – T-cells and B-cells from a specific immune reaction that continue to circulate in the body even after the infection is resolved. They "remember" specific antigens and can multiple rapidly upon subsequent exposure, creating an immediate immune response already trained to eliminate the threat.

**Monoclonal antibodies (mAbs)** – Antibodies made in a laboratory that are designed to target specific parts of cancer cells, which may include certain proteins or molecules on the surface of the cancer cells; they are meant to stimulate an immune response in the same way as naturally produced antibodies do.

**Natural killer cells** – White blood cells that contain enzymes that kill virally infected cells and tumor cells. They also communicate with T-cells to help regulate their development and response.

**Oncolytic virus** – A virus that can infect and multiply within cancer cells, leading them to die. These viruses may be manufactured or naturally occurring, and can be used to target and destroy specific tumor cells. They may also induce an immune response.

PD-1 (programmed cell death-1) — The receptor in the PD-1 checkpoint pathway that sends negative signals to the T-cell when it connects to a PD-1 or PD-2 ligand (PD-L1 or PD-L2). These negative signals normally slow down or stop the immune response when it's no longer necessary. Certain cancer cells have the ability to influence the engagement of this checkpoint, which puts the brakes on the immune response.

Proliferation - Cell division and development (growth).

Receptors (immune receptors) – Proteins on the surface of immune cells that bind to ligands on the surface of other immune cells. This connection typically results in immune cell signaling that regulates specific immune system functions.

Regulatory T-cells — T-cells that help maintain the necessity, strength and duration of an immune response by regulating T-cell activity. They shut down the other T-cells at the end of an immune reaction. Certain tumor cells have the ability to increase regulatory T-cell activity, which decreases the overall immune response.

Signal 1, Signal 2 — The primary and secondary cell signals necessary for the immune system to activate. Signal 1 is the interaction between the antigen-presenting cell and the T-cell through a connection between the major histocompatibility complex (MHC) and a T-cell receptor. Signal 2 can be any number of connections formed by the molecules and receptors on the surfaces of both the antigen-presenting cell and the T-cell.

**Standard of care** — A treatment regimen that is accepted by medical experts and is widely used as a treatment for a specific type of cancer. This can also be called best practice, standard medical care and standard therapy.

**T-cells** – Immune cells that recognize specific antigens during antigen presentation. T-cells are the major players in the immune system's fight against cancer. Their activation and activity are two of the main focuses in immunotherapy research.

T-cell receptors (TCRs) — Molecules found only on the surface of T-cells. TCRs must bind to special molecules on the surface of antigen-presenting cells before they can receive information about a threat. This connection is the first signal (Signal 1) necessary to activate the T-cell to respond to the tumor.

**Tumor microenvironment** – The area surrounding a tumor, inside which normal cells, molecules and blood vessels help sustain the tumor. The microenvironment contributes to the behavior, proliferation and spread of the tumor; the tumor itself is capable of affecting its own microenvironment.

**Upregulate** – Increase either the overall immune system response or the specific responses of certain immune cells.

# **ABOUT CLINICAL TRIALS**

#### Clinical trials are research studies

that evaluate the safety and effectiveness of new treatments and help identify which treatments work best for certain illnesses or groups of people. Clinical trials often offer opportunities for patients to access cutting edge treatments that are not yet widely available. Talk with your doctor to determine if a clinical trial is a good choice for you.

To qualify, you must meet certain eligibility criteria, such as cancer type, overall health and treatment history. Immunotherapy depends on immune system function, so a properly functioning immune system is often a qualifying factor.

Clinical trials evaluating immunotherapy, alone and combined with other treatments, that are open for recruitment as of November 9, 2016, are listed on pages 16-34. To

learn about a specific trial, enter the trial record number (NCT) into the search box located at the top of the Web page. The trial record number is a unique identification code assigned to each clinical study. The trial will be "Recruiting" or "Not yet recruiting," which means the studies are either actively looking for participants or getting ready to look for participants. If you locate a trial that is not recruiting, don't be discouraged. New studies happen all the time, so keep checking to find available trials.

# CANCER IMMUNOTHERAPY CLINICAL TRIALS BY DISEASE

Includes all studies categorized as "cancer immunotherapy" (as of November 9, 2016) by the U.S. National Institutes of Health at www.clinicaltrials.gov.

#### ANAL

Title	Cancer Type	Treatment	Location	NCT Number
E7 TCR T Cells With or Without PD-1 Blockade for Human Papillomavirus-Associated Cancers	Cervical Cancer; Vaginal Cancer; Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Biological: E7 TCR cells; Drug: pembrolizumab; Drug: aldesleukin; Drug:	MD	NCT02858310
•	. , ,	fludarabine; Drug: cyclophosphamide		

#### **BLADDER**

Title	Cancer Type	Treatment	Location	NCT Number
Evaluation for NCI Surgery Branch Clinical Studies	Synovial Cell Cancer; Melanoma; Colorectal Cancer; Lung Cancer; Bladder Cancer		MD	NCT00001823
Study of Bacillus Calmette-Guerin (BCG) Combined With PANVAC Versus BCG Alone in Adults With High Grade Non-Muscle Invasive Bladder Cancer Who Failed At Least 1 Course of BCG	Bladder Cancer	Biological: TICE Bacillus Calmette-Guerin (BCG); Biological: PANVAC	MD; NJ	NCT02015104
A Study of Intravesical Bacillus Calmette-Guerin (BCG) in Combination With ALT-803 in Patients With Non-Muscle Invasive Bladder Cancer	Non-muscle Invasive Bladder Cancer	Biological: BCG+ALT-803; Biological: BCG	AK; AL; CA; HI; NH; NY; OH	NCT02138734
Phase I/lb Study of Pembrolizumab With Vorinostat for Patients With Advanced Renal or Urothelial Cell Carcinoma	Renal Cell Carcinoma; Urinary Bladder Neoplasms	Drug: Pembrolizumab; Drug: Vorinostat	IN; MD	NCT02619253
Pembrolizumab (MK3475), Gemcitabine, and Concurrent Hypofractionated Radiation Therapy for Muscle-Invasive Urothelial Cancer of the Bladder	Muscle-invasive Urothelial Cancer of the Bladder	Biological: Pembrolizumab; Procedure: Transurethral Resection of Bladder Tumor; Drug: Gemcitabine; Radiation: External Beam Radiation Therapy	NY	NCT02621151
A Personalized Cancer Vaccine (NEO-PV-01) w/ Nivolumab for Patients With Melanoma, Lung Cancer or Bladder Cancer	Urinary Bladder Cancer; Bladder Tumors; Transitional Cell Carcinoma of the Bladder; Malignant Melanoma; Melanoma; Skin Cancer; Carcinoma, Non-Small-Cell Lung; Lung Cancer	Biological: NEO-PV-01; Biological: Nivolumab; Other: Adjuvant	CA; MA; TX	NCT02897765

#### **BRAIN**

Title	Cancer Type	Treatment	Location	NCT Number	
Vaccine Immunotherapy for Recurrent Medulloblastoma and Primitive Neuroectodermal Tumor	Medulloblastoma; Neuroectodermal Tumor	Biological: TTRNA-xALT; Biological: TTRNA-DCs	CA; DC; FL; NC	NCT01326104	
CAR T Cell Receptor Immunotherapy Targeting EGFRvIII for Patients With Malignant Gliomas Expressing EGFRvIII	Malignant Glioma; Glioblastoma; Brain Cancer	Biological: Anti-EGFRVIII CAR transduced PBL; Drug: Aldesleukin; Drug: Fludarabine; Drug: Cyclophosphamide	MD	NCT01454596	
Imiquimod and Tumor Lysate Vaccine Immunotherapy in Adults With High Risk or Recurrent Grade II Gliomas	High Risk WHO Grade II Glioma; Recurrent/ Post-Chemotherapy WHO Grade II Glioma	Biological: Tumor Lysate Vaccine; Drug: Imiquimod	PA	NCT01678352	
Photodynamic Therapy (PDT) For Recurrent High Grade Gliomas	Brain Tumor, Recurrent	Drug: Photofrin photodynamic therapy.	WI	NCT01966809	
Phase I Study of Safety and Immunogenicity of ADU-623	Astrocytic Tumors; Glioblastoma Multiforme; Anaplastic Astrocytoma; Brain Tumor	Biological: Cohort 1; Biological: Cohort 2; Biological: Cohort 3; Drug: Antibiotics	OR	NCT01967758	
Phase I Study of a Dendritic Cell Vaccine for Patients With Either Newly Diagnosed or Recurrent Glioblastoma	Glioblastoma; Glioblastoma Multiforme; Glioma; Astrocytoma; Brain Tumor	Biological: Dendritic cell vaccination, in addition to standard temozolomide chemotherapy and involved field radiation therapy, Biological: Dendritic cell vaccination, with optional bevacizumab treatment for patients previously treated with bevacizumab	CA	NCT02010606	
A Phase I Trial of T Cells Expressing an Anti-GD2 Chimeric Antigen Receptor in Children and Young Adults With GD2+ Solid Tumors	Sarcoma; Osteosarcoma; Neuroblastoma; Melanoma	Biological: Anti-GD2-CAR engineered T cells; Drug: AP1903; Drug: Cyclophosphamide	MD	NCT02107963	

# **BRAIN** (CONTINUED)

BRAIN (CONTINUED) Title	Cancer Type	Treatment	Location	NCT Number
IDH1 Peptide Vaccine for Recurrent Grade II Glioma	Brain Cancer; Brain Neoplasm, Primary; Brain	Biological: PEPIDH1M vaccine	NC	NCT02193347
	Neoplasms, Recurrent; Brain Tumor; Cancer of the Brain	g		
DNX-2401 With Interferon Gamma (IFN-y) for Recurrent Glioblastoma or Gliosarcoma Brain Tumors	Glioblastoma or Gliosarcoma	Drug: Single intratumoral injection of DNX-2401; Drug: Interferon-gamma	AR; FL; OH; TX	NCT02197169
Genetically Modified T-cells in Treating Patients With Recurrent or Refractory Malignant Glioma	Malignant Glioma; Refractory Brain Neoplasm; Recurrent Brain Neoplasm	Biological: IL13Rα2-specific, hinge- optimized, 41BB-costimulatory CAR/ truncated CD19-expressing T lymphocytes; Other: laboratory biomarker analysis; Other: quality-of-life assessment; Procedure: Magnetic Resonance Imaging; Procedure: Magnetic Resonance Spectroscopic Imaging	CA	NCT02208362
Phase 2 Study of MEDI4736 in Patients With Glioblastoma	Glioblastoma	Drug: MEDI4736; Radiation: Radiotherapy; Biological: Bevacizumab	CA; MA; MD; M0; NY	NCT02336165
A Pilot Study to Evaluate PBR PET in Brain Tumor Patients Treated With Chemoradiation or Immunotherapy	Intracranial Tumors; Glioblastoma; Melanoma	Other: PBR PET; Biological: Cancer Immunotherapy; Radiation: Radiation and chemotherapy	MA	NCT02431572
Using Ferumoxytol-Enhanced MRI to Measure Inflammation in Patients With Brain Tumors or Other Conditions of the CNS	Brain Injury; Central Nervous System Degenerative Disorder; Central Nervous System Infectious Disorder; Central Nervous System Vascular Malformation; Hemorrhagic Cerebrovascular Accident; Ischemic Cerebrovascular Accident; Primary Brain Neoplasm; Brain Cancer; Brain Tumors	Drug: Ferumoxytol; Other: Tissue Analysis; Procedure: Magnetic Resonance Imaging	CA	NCT02452216
HSV G207 Alone or With a Single Radiation Dose in Children With Progressive or Recurrent Supratentorial Brain Tumors	Supratentorial Neoplasms, Malignant	Biological: G207	AL	NCT02457845
Study of the IDO Pathway Inhibitor, Indoximod, and Temozolomide for Pediatric Patients With Progressive Primary Malignant Brain Tumors	Glioblastoma Multiforme; Glioma; Gliosarcoma; Malignant Brain Tumor; Ependymoma; Medulloblastoma	Drug: Indoximod; Drug: Temozolomide; Radiation: Conformal Radiation	GA	NCT02502708
Antisense102: Pilot Immunotherapy for Newly Diagnosed Malignant Glioma	Malignant Glioma; Neoplasms	Drug: IGF-1R/AS ODN; Surgery with tissue harvest and implantation 10 diffusion chambers in the rectus sheath with IGF-1R/AS ODN within 24 hours of craniotomy, implanted for 24 hours.; Drug: IGF-1R/AS ODN; Surgery with tissue harvest and implantation 10 diffusion chambers in the rectus sheath with IGF-1R/AS ODN within 24 hours of craniotomy, implanted for 48 hours.; Drug: IGF-1R/AS ODN; Surgery with tissue harvest and implantation of 20 diffusion chambers in the rectus sheath with IGF-1R/AS ODN within 24 hours of craniotomy, implanted for 24 hours.; Drug: IGF-1R/AS ODN; Surgery with tissue harvest and implantation of 20 diffusion chambers in the rectus sheath with IGF-1R/AS ODN within 24 hours of craniotomy, implanted for 48 hours.	PA	NCT02507583
Nivolumab With DC Vaccines for Recurrent Brain Tumors	Malignant Glioma; Astrocytoma; Glioblastoma	Drug: nivolumab; Biological: DC	NC	NCT02529072
Neo-adjuvant Evaluation of Glioma Lysate Vaccines in WHO Grade II Glioma	Oligodendroglioma; Astrocytoma, Grade II; Glioma, Astrocytic; Glioma; Malignant Glioma; Oligoastrocytoma, Mixed	Biological: GBM6-AD and poly-ICLC before and after surgery; Biological: GBM6-AD and poly-ICLC after surgery only	CA	NCT02549833
Stereotactic Radiosurgery With Nivolumab and Valproate in Patients With Recurrent Glioblastoma	Glioblastoma	Radiation: Stereotactic Radiosurgery; Drug: Nivolumab; Drug: Valproate	VA	NCT02648633
A Study of Nivolumab in Adult Participants With Recurrent High-Grade Meningioma	Meningiomas	Drug: Nivolumab	MA	NCT02648997
A Study to Evaluate the Safety, Tolerability and Immunogenicity of EGFR(V)-EDV-Dox in Subjects With Recurrent Glioblastoma Multiforme (GBM)	Glioblastoma; Astrocytoma, Grade IV	Drug: EGFR(V)-EDV-Dox	MD	NCT02766699
Combination Adenovirus + Pembrolizumab to Trigger Immune Virus Effects	Brain Cancer; Brain Neoplasm; Glioma; Glioblastoma; Gliosarcoma; Malignant Brain Tumor; Neoplasm, Neuroepithelial; Neuroectodermal Tumors; Neoplasm by Histologic Type; Neoplasm, Nerve Tissue; Nervous System Diseases	Biological: DNX-2401; Biological: pembrolizumab	AR; NY; UT	NCT02798406
A Pilot Surgical Trial To Evaluate Early Immunologic Pharmacodynamic Parameters For The PD-1 Checkpoint Inhibitor, Pembrolizumab (MK-3475), In Patients With Surgically Accessible Recurrent/Progressive Glioblastoma	Brain Cancer	Drug: MK-3475	MA	NCT02852655
A Study of Varlilumab and IMA950 Vaccine Plus Poly-ICLC in Patients With WHO Grade II Low-Grade Glioma (LGG)	Glioma; Malignant Glioma; Astrocytoma, Grade II; Oligodendroglioma; Glioma, Astrocytic; Oligoastrocytoma, Mixed	Biological: IMA950; Biological: poly-ICLC; Biological: Varlilumab	CA	NCT02924038

# BREAST

Title	Cancer Type	Treatment	Location	NCT Number
Vaccine Therapy in Treating Patients With Metastatic Solid Tumors	Malignant Solid Tumour; Breast Cancer; Malignant Tumor of Colon; GIST; Ovarian Cancer	Biological: HER-2 vaccine	OH	NCT01376505
Toll-like Receptor (TLR) 7 Agonist, Cyclophosphamide, and Radiotherapy for Breast Cancer With Skin Metastases	Breast Cancer; Metastatic Breast Cancer; Recurrent Breast Cancer	Radiation: Radiation; Drug: Imiquimod; Drug: Cyclophosphamide	NY	NCT01421017
Combination Immunotherapy With Herceptin and the HER2 Vaccine NeuVax	Breast Cancer	Drug: Herceptin; Drug: NeuVax vaccine; Drug: GM-CSF	CA; CO; DC; FL; HI; IN; KS; MD; NJ; NY; OR; PA; TX; VA; WA; WI	NCT01570036
Stereotactic Body Radiation and Monoclonal Antibody to OX40 (MEDI6469) in Breast Cancer Patients With Metastatic Lesions	Metastatic Breast Cancer; Lung Metastases; Liver Metastases	Biological: MEDI6469	OR	NCT01862900
T Cell Receptor Immunotherapy Targeting NY-ESO-1 for Patients With NY-ESO-1 Expressing Cancer	Synovial Sarcoma; Breast Cancer; Non-Small Cell Lung Cancer; Hepatocellular Cancer	Biological: Anti-NY ESO-1 mTCR PBL; Drug: Cyclophosphamide; Drug: Fludarabine; Drug: Aldesleukin	MD	NCT01967823
A Phase 1 Study of AM0010 in Patients With Advanced Solid Tumors	Melanoma; Prostate Cancer; Ovarian Cancer; Renal Cell Carcinoma; Colorectal Carcinoma; Pancreatic Carcinoma; Non-small Cell Lung Carcinoma; Solid Tumors; Breast Cancer	Drug: AM0010; Drug: Paclitaxel or Docetaxel and Carboplatin or Cisplatin; Drug: FOLFOX (Oxaliplatin/Leucovorin/ 5-Fluorouracil); Drug: Gemcitabine/ nab-paclitaxel; Drug: Capecitabine; Drug: Pazopanib; Drug: Pembrolizumab; Drug: Paclitaxel; Drug: nivolumab; Drug: Gemcitabine/carboplatin	CA; CO; FL; MA; NY; OK; TN; TX	NCT02009449
DC Vaccine for Patients With Ductal Carcinoma In Situ	Breast Cancer; DCIS	Biological: HER-2 Pulsed Dendritic cell Vaccine	PA	NCT02061332
Phase II Trial of Combination Immunotherapy With NeuVax and Trastuzumab in High-risk HER2+ Breast Cancer Patients	Breast Cancer	Biological: NeuVax vaccine; Drug: Trastuzumab; Drug: GM-CSF	AZ; CA; CO; DC; FL; IL; IN; KS; MD; MN; NJ; NM; NY; PA; TX; VA; WA; WI	NCT02297698
Trial of Active Immunotherapy With OBI-833 (Globo H-CRM197)in Gastric, Lung, Colorectal or Breast Cancer Subjects	Metastatic Gastric Cancer; Metastatic Breast Cancer; Metastatic Colorectal Cancer; Metastatic Lung Cancer	Drug: OBI-833/OBI-821	OH; TX	NCT02310464
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer; Head and Neck Squamous Cell Cancer; Ovarian Cancer; Colorectal Cancer; Gastric Cancer; Esophageal Cancer; Hepatocellular Cancer	Biological: INO-1400; Biological: INO-9012	MI; NC; PA	NCT02327468
Malignant Pleural Disease Treated With Autologous T Cells Genetically Engineered to Target the Cancer-Cell Surface Antigen Mesothelin	Malignant Pleural Disease; Mesothelioma; Metastases; Lung Cancer; Breast Cancer	Genetic: iCasp9M28z T cell infusions; Drug: cyclophosphamide	NY	NCT02414269
A Study of Ad-RTS-hIL-12 With Veledimex in Subjects With Breast Cancer	Metastatic Breast Cancer	Biological: Ad-RTS-hIL-12; Drug: Veledimex	NY	NCT02423902
Standard of Care Chemotherapy Plus Pembrolizumab for Breast Cancer	Triple Negative Breast Cancer	Drug: Pembrolizumab; Drug: Paclitaxel; Drug: Capecitabine	OR	NCT02734290
T-Cell Therapy for Advanced Breast Cancer	Breast Cancer; Metastatic HER2-negative Breast	Drug: Cyclophosphamide; Biological: Mesothelin-targeted T cells; Drug: AP1903	NJ; NY	NCT02792114
Adjuvant PVX-410 Vaccine and Durvalumab in Stage II/III Triple Negative Breast Cancer	Breast Cancer	Biological: PVX-410; Biological: Durvalumab; Drug: Hiltonol	MA	NCT02826434
Trial of Intratumoral Injections of TTI-621 in Subjects With Relapsed and Refractory Solid Tumors and Mycosis Fungoides	Solid Tumors; Mycosis Fungoides; Melanoma; Merkel-cell Carcinoma; Squamous Cell Carcinoma; Breast Carcinoma; Human Papillomavirus-Related Malignant Neoplasm; Soft Tissue Sarcoma	Drug: TTI-621	CA; OR; PA; WA	NCT02890368
Pre-operative IRX-2 in Early Stage Breast Cancer (ESBC)	Breast Neoplasm; Breast Neoplasm, Male	Drug: Cyclophosphamide; Drug: Indomethacin; Drug: Omeprazole; Dietary Supplement: Multivitamin	OR	NCT02950259
Neoadj Pembrolizumab + Decitabine Followed by Std Neoadj Chemo for Locally Advanced HER2- Breast Cancer	Locally Advanced Breast Cancer, Invasive Adenocarcinoma of the Breast, Breast Cancer Stage II; Breast Cancer Stage III; Breast Cancer Stage IV	Drug: Doxorubicin; Drug: Cyclophosphamide; Drug: Paclitaxel; Drug: Carboplatin	VA	NCT02957968

#### **CERVICAL**

Title	Cancer Type	Treatment	Location	NCT Number
CAR T Cell Receptor Immunotherapy Targeting Mesothelin for Patients With Metastatic Cancer	Cervical Cancer; Pancreatic Cancer; Ovarian Cancer; Mesothelioma; Lung Cancer	Drug: Fludarabine; Biological: Anti- mesothelin CAR; Drug: Cycolphosphamide; Drug: Aldesleukin	MD	NCT01583686
Pembrolizumab and Chemoradiation Treatment for Advanced Cervical Cancer	Cervical Cancer	Drug: Pembrolizumab; Radiation: Brachytherapy; Drug: Cisplatin	VA	NCT02635360
E7 TCR T Cells With or Without PD-1 Blockade for Human Papillomavirus-Associated Cancers	Cervical Cancer; Vaginal Cancer, Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Biological: E7 TCR cells; Drug: pembrolizumab; Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide	MD	NCT02858310

#### COLORECTAL

Title	Cancer Type	Treatment	Location	NCT Number
Evaluation for NCI Surgery Branch Clinical Studies	Synovial Cell Cancer; Melanoma; Colorectal Cancer; Lung Cancer; Bladder Cancer		MD	NCT00001823
Immunotherapy Using Tumor Infiltrating Lymphocytes for Patients With Metastatic Cancer	Metastatic Colorectal Cancer; Metastatic Gastric Cancer; Metastatic Pancreatic Cancer; Metastatic Hepatocellular Carcinoma; Metastatic Cholangiocarcinoma	Biological: Young TlL; Drug: Aldesleukin; Drug: Cyclophosphamide; Drug: Fludarabine; Drug: Pembrolizumab	MD	NCT01174121
Immunotherapy With CEA(6D) VRP Vaccine (AVX701) in Patients With Stage III Colorectal Cancer	Stage III Colon Cancer	Biological: AVX701	NC	NCT01890213
A Phase 1 Study of AM0010 in Patients With Advanced Solid Tumors	Melanoma; Prostate Cancer; Ovarian Cancer; Renal Cell Carcinoma; Colorectal Carcinoma; Pancreatic Carcinoma; Non-small Cell Lung Carcinoma; Solid Tumors; Breast Cancer	Drug: AM0010; Drug: Paclitaxel or Docetaxel and Carboplatin or Cisplatin; Drug: FOLFOX (Oxaliplatin/Leucovorin/5- Fluorouracil); Drug: apencitabine/ nab-paclitaxel; Drug: Capecitabine; Drug: Pazopanib; Drug: Pembrolizumab; Drug: Paclitaxel; Drug: nivolumab; Drug: Gemcitabine/carboplatin	CA; CO; FL; MA; NY; OK; TN; TX	NCT02009449
Trial of Active Immunotherapy With OBI-833 (Globo H-CRM197)in Gastric, Lung, Colorectal or Breast Cancer Subjects	Metastatic Gastric Cancer; Metastatic Breast Cancer; Metastatic Colorectal Cancer; Metastatic Lung Cancer	Drug: OBI-833/OBI-821	OH; TX	NCT02310464
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer; Head and Neck Squamous Cell Cancer; Ovarian Cancer; Colorectal Cancer; Gastric Cancer; Esophageal Cancer; Hepatocellular Cancer	Biological: INO-1400; Biological: INO-9012	MI; NC; PA	NCT02327468
Increased Frequency of AlloStim Immunotherapy Dosing in Combination With Cryoablation in Metastatic Colorectal Cancer	Colorectal Cancer Metastatic	Biological: AlloStim; Procedure: Cryoablation	AZ	NCT02380443
A Multicenter Study of Active Specific Immunotherapy With OncoVax in Patients With Stage II Colon Cancer	Stage II Colon Cancer	Biological: OncoVAX and Surgery; Procedure: Surgery	FL	NCT02448173
Anti-OX40 Antibody (MEDI6469) in Patients With Metastatic Colorectal Cancer	Colorectal Neoplasms	Drug: MEDI6469	OR	NCT02559024
Pembrolizumab + Poly-ICLC in MRP Colon Cancer	Metastatic Colon Cancer; Solid Tumor	Drug: pembrolizumab; Drug: Poly-ICLC	GA	NCT02834052
Study of Cobimetinib in Combination With Atezolizumab and Bevacizumab in Participants With Gastrointestinal and Other Tumors	Colorectal Cancer	Drug: Atezolizumab; Drug: Bevacizumab; Drug: Cobimetinib	CO; NY; TN; TX	NCT02876224

# FALLOPIAN TUBE

Title	Cancer Type	Treatment	Location	NCT Number
PARP-inhibition and CTLA-4 Blockade in BRCA-deficient Ovarian Cancer	Ovarian Cancer; Fallopian Tube Cancer; Peritoneal Neoplasms	Drug: Olaparib; Drug: Tremelimumab	NM	NCT02571725
GL-ONC1 Oncolytic Immunotherapy in Patients With Recurrent Ovarian Cancer	Ovarian Cancer; Peritoneal Carcinomatosis; Fallopian Tube Cancer	Biological: GL-ONC1	FL	NCT02759588
Study of DPX-Survivac Vaccine Therapy and Epacadostat in Patients With Recurrent Ovarian Cancer	Recurrent Epithelial Ovarian Cancer; Recurrent Fallopian Tube Cancer; Recurrent Peritoneal Cancer	Biological: DPX-Survivac; Drug: Cyclophosphamide; Drug: Epacadostat (INCB024360)	NY; OR; TX	NCT02785250
Intraperitoneal Infusion of Autologous Monocytes With Sylatron (Peginterferon Alfa-2b) and Actimmune (Interferon Gamma-1b) in Women With Recurrent or Refractory Ovarian Cancer, Fallopian Tube Cancer or Primary Peritoneal Cancer	Fallopian Tube Cancer; Ovarian Cancer; Primary Peritoneal Cancer	Biological: Autologous Monocytes + ACTIMMUNE + SYLATRON	MD	NCT02948426

# **HEAD & NECK**

Title	Cancer Type	Treatment	Location	NCT Number
ADXS 11-001 Vaccination Prior to Robotic Surgery, HPV- Positive Oropharyngeal Cancer	Head and Neck Cancer; Squamous Cell Carcinoma of the Head and Neck; Human Papillomavirus Positive Oropharyngeal Squamous Cell Carcinoma	Biological: ADXS11-001 (ADXS-HPV)	NY	NCT02002182
TGF-beta Resistant Cytotoxic T-lymphocytes in Treatment of EBV-positive Nasopharyngeal Carcinoma / RESIST-NPC	EBV-positive Nasopharyngeal Carcinoma	Genetic: DNR.NPC-specific T cells; Genetic: DNR.NPC-specific T cells + cyclophosphamide + fludarabine	TX	NCT02065362
Anti-OX40 Antibody in Head and Neck Cancer Patients	Head and Neck Cancer	Drug: Anti-OX40 antibody administration; Procedure: Surgical Resection	OR	NCT02274155
Immunotherapy With MK-3475 in Surgically Resectable Head and Neck Squamous Cell Carcinoma	Cancer of Head and Neck; Head and Neck Cancer; Neoplasms, Head and Neck; Carcinoma, Squamous Cell of Head and Neck; Squamous Cell Carcinoma of the Head and Neck; Squamous Cell Carcinoma, Head and Neck	Biological: MK-3475; Procedure: Surgery; Radiation: Intensity modulated radiation therapy; Radiation: Image-guided radiation therapy; Drug: Cisplatin	MA; MO	NCT02296684
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer; Head and Neck Squamous Cell Cancer; Ovarian Cancer; Colorectal Cancer; Gastric Cancer; Esophageal Cancer; Hepatocellular Cancer	Biological: INO-1400; Biological: INO-9012	MI; NC; PA	NCT02327468

# **HEAD & NECK** (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
A Phase 1b/2 Study of MEDI4736 With Tremelimumab, MEDI4736 or Tremelimumab Monotherapy in Gastric or GEJ Adenocarcinoma	Gastric or Gastroesophageal Junction Adenocarcinoma	Biological: MEDI4736 + tremelimumab; Biological: MEDI4736; Biological: Tremelimumab; Biological: MEDI4736 + tremelimumab	CA; CT; FL; IL; MD; NY; OH; OR; PA; SC; TN; TX	NCT02340975
Administering Peripheral Blood Lymphocytes Transduced With a Murine T-Cell Receptor Recognizing Human Thyroglobulin to People With Thyroglobulin Expressing Thyroid Cancer	Metastatic Thyroid Cancer	Drug: Aldesleukin; Drug: Fludarabine; Drug: Cyclophosphamide; Biological: Anti- Thyroglobulin mTCR PBL	MD	NCT02390739
In Situ, Autologous Therapeutic Vaccination Against Solid Cancers With Intratumoral Hiltonol	Melanoma; Head and Neck Cancer; Sarcoma; Non-Melanoma Skin Cancers	Biological: Hiltonol	GA; MD; NY; PA	NCT02423863
Multicentre, Randomized, Open-Label, Phase III Clinical Trial for Advanced Nasopharyngeal Carcinoma Patients	Nasopharyngeal Cancer	Biological: autologous EBV specific Cytotoxic T Lymphocytes; Drug: combination IV gemcitabine and IV carboplatin (AUC2)	CA; TX	NCT02578641
IRX-2 Regimen in Patients With Newly Diagnosed Stage III or IVA Squamous Cell Carcinoma of the Oral Cavity	Squamous Cell Carcinoma of the Oral Cavity	Biological: IRX-2; Drug: Cyclophosphamide; Drug: Indomethacin; Dietary Supplement: Zinc-containing multivitamin; Drug: Omeprazole	AR; AZ; CA; DC; GA; KY; MA; MI; NE; NY; OK; OR; PA	NCT02609386
Combination Margetuximab and Pembrolizumab for Advanced, Metastatic HER2(+) Gastric or Gastroesophageal Junction Cancer	Gastric Cancer; Stomach Cancer; Esophageal Cancer	Drug: margetuximab in combination with pembrolizumab	CT; DC; IL; MA; MD; MI; MO; NC; PA; TN; WA	NCT02689284
Chemotherapy +/- Nivolumab in Patients With Intermediate and High-Risk Local-Regionally Advanced Head and Neck Squamous Cell Carcinoma	Head and Neck Squamous Cell Carcinoma (HNSCC)	Drug: Nivolumab; Drug: Cisplatin; Drug: Cetuximab; Radiation: IMRT	ОН	NCT02764593
Ipilimumab for Head and Neck Cancer Patients	Squamous Cell Carcinoma of the Head and Neck	Drug: Intratumoral Ipilimumab	OR	NCT02812524
E7 TCR T Cells With or Without PD-1 Blockade for Human Papillomavirus-Associated Cancers	Cervical Cancer; Vaginal Cancer; Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Biological: E7 TCR cells; Drug: pembrolizumab; Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide	MD	NCT02858310

#### **KIDNEY**

Title	Cancer Type	Treatment	Location	NCT Number
High Dose IL-2 and Stereotactic Ablative Body Radiation Therapy for Metastatic Renal Cancer	Metastatic Clear Cell Renal Cell Carcinoma	Drug: IL-2; Radiation: Stereotactic Ablative Body Radiation Therapy	TX	NCT01896271
A Phase 1 Study of AM0010 in Patients With Advanced Solid Tumors	Melanoma; Prostate Cancer; Ovarian Cancer; Renal Cell Carcinoma; Colorectal Carcinoma; Pancreatic Carcinoma; Non-small Cell Lung Carcinoma; Solid Tumors; Breast Cancer	Drug: AM0010; Drug: Paclitaxel or Docetaxel and Carboplatin or Cisplatin; Drug: FOLFOX (Oxaliplatin/Leucovorin/5-Fluorouracil); Drug: gemcitabine/nab-paclitaxel; Drug: Capecitabine; Drug: Pacopanib; Drug: Pembrolizumab; Drug: Paclitaxel; Drug: nivolumab; Drug: Gemcitabine/carboplatin	CA; CO; FL; MA; NY; OK; TN; TX	NCT02009449
Vaccine Therapy Before Surgery in Treating Patients With Localized Kidney Cancer	Recurrent Renal Cell Carcinoma; Stage I Renal Cell Cancer; Stage II Renal Cell Cancer	Other: Laboratory Biomarker Analysis; Procedure: Nephrectomy; Biological: Renal Cell Carcinoma/CD40L RNA-Transfected Autologous Dendritic Cell Vaccine AGS-003	NY	NCT02170389
Study of Neoadjuvant Nivolumab in Patients With Non-metastatic Stage II-IV Clear Cell Renal Cell Carcinoma	Clear Cell Renal Cell Carcinoma	Drug: Nivolumab	MD	NCT02575222
Phase I/lb Study of Pembrolizumab With Vorinostat for Patients With Advanced Renal or Urothelial Cell Carcinoma	Renal Cell Carcinoma; Urinary Bladder Neoplasms	Drug: Pembrolizumab; Drug: Vorinostat	IN; MD	NCT02619253
Single Agent Pembrolizumab in Subjects With Advanced Adrenocortical Carcinoma	Adrenocortical Carcinoma	Drug: Pembrolizumab	NY	NCT02673333

# LEUKEMIA/LYMPHOMA/MULTIPLE MYELOMA

Title	Cancer Type	Treatment	Location	NCT Number
Biological Therapy in Treating Patients at High-Risk or With Lymphoma, Lymphoproliferative Disease, or Malignancies	Leukemia; Lymphoma; Unspecified Adult Solid Tumor, Protocol Specific; Unspecified Childhood Solid Tumor, Protocol Specific	Biological: allogeneic Epstein-Barr virus- specific cytotoxic T lymphocytes	NY	NCT00002663
A Treatment-Option Protocol to Provide Brentuximab Vedotin to Eligible Patients Completing Studies SGN35-005 or C25001	Disease, Hodgkin; Lymphoma, Large-Cell, Anaplastic; Lymphoma, Non-Hodgkin; Lymphoma, T-Cell, Cutaneous	Drug: brentuximab vedotin	CA; MA; TX	NCT01196208
Immunotherapy for Asymptomatic Phase Lymphoplasmacytic Lymphoma	Lymphoma; Lymphoplasmacytic Lymphoma; Waldenström Macroglobulinemia	Biological: DNA Vaccine	TX	NCT01209871
Th1/Tc1 Immunotherapy Following Stem Cell Transplantation in Multiple Myeloma	Multiple Myeloma	Procedure: Adoptive Immunotherapy; Biological: Rapamycin-Generated Autologous Th1/Tc1 Cells	DC; MD; NJ	NCT01239368
Trial of Daily Pulse Interleukin-2 With Famotidine in Acute Myelogenous Leukemia	Acute Myelogenous Leukemia	Drug: Interleukin-2	NC	NCT01289678
Continuous Infusion of rhIL-15 for Adults With Advanced Cancer	Lymphoma; Carcinoma	Biological: rh IL-15	MD	NCT01572493

# LEUKEMIA/LYMPHOMA/MULTIPLE MYELOMA (CONTINUED)

Tidle	ConserTime	Transment	Lanction	NCT Number
Title  Randomized, Open-label, Two-arms, Phase III Comparative Study Assessing the Role of Involved Mediastinal Radiotherapy After Rituximab Containing Chemotherapy Regimens to Patients With Newly Diagnosed Primary Mediastinal Large B-Cell Lymphoma	Cancer Type  Primary Mediastinal B-cell Lymphoma	Treatment  Other: observation; Radiation: 3D-Conformal Radiotherapy (3D-CRT)	MN; NE	NCT Number NCT01599559
Allogeneic Stem Cell Transplantation With Adoptive Immunotherapy in Epstein-Barr Virus Positive Recurrent/ Refractory Hodgkins Lymphoma	Hodgkins Lymphoma	Biological: allogeneic donor derived LMP specific cytotoxic T-lymphocyte	NY	NCT01636388
Therapy for Pediatric Relapsed or Refractory Precursor B-Cell Acute Lymphoblastic Leukemia and Lymphoma	Recurrent B-Cell Childhood Acute Lymphoblastic Leukemia; Recurrent Childhood B-Lymphoblastic Lymphoma	Drug: dexamethasone; Drug: vincristine sulfate; Biological: rituximab; Drug: clofarabine; Drug: cyclophosphamide; Drug: etoposide; Biological: aldesleukin; Drug: pegaspargase; Drug: methotrexate; Drug: mercaptopurine; Drug: cytarabine; Drug: mitoxantrone; Drug: teniposide; Drug: vinblastine; Biological: natural killer cell infusion; Other: laboratory biomarker analysis; Drug: therapeutic hydrocortisone; Procedure: allogeneic hematopoietic stem cell transplantation	CA; TN; TX	NCT01700946
Phase I Dose Escalation Study of IMMU-114 in Relapsed or Refractory NHL and CLL	Non-hodgkin's Lymphoma; Follicular Lymphoma; Mantle Cell Lymphoma; Marginal Zone Lymphoma; Chronic Lymphocytic Leukemia; Small Lymphocytic Lymphoma	Drug: IMMU-114	DE; GA; IN; OH; UT	NCT01728207
Treatment for Advanced B-Cell Lymphoma	Diffuse Large Cell Lymphoma; Burkitt's Lymphoma; High Grade B-cell Lymphoma	Drug: Rituximab; Drug: IT Cytarabine	NC; NY; OK; UT	NCT01859819
T-Lymphocytes Genetically Targeted to the B-Cell Specific Antigen CD19 in Pediatric and Young Adult Patients With Relapsed B-Cell Acute Lymphoblastic Leukemia	Relapsed B-Cell Acute Lymphoblastic Leukemia	Procedure: leukapheresis or collection of PBMCs; Drug: cyclophosphamide based chemotherapy regimens; Biological: modified T cells	MA; NY	NCT01860937
Laboratory Treated T Cells in Treating Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia, Non-Hodgkin Lymphoma, or Acute Lymphoblastic Leukemia	Recurrent Adult Acute Lymphoblastic Leukemia; Recurrent Chronic Lymphocytic Leukemia; Recurrent Diffuse Large B-Cell Lymphoma; Recurrent Mantle Cell Lymphoma; Recurrent Non-Hodgkin Lymphoma; Recurrent Small Lymphocytic Lymphoma; Refractory Chronic Lymphocytic Leukemia; Refractory Diffuse Large B-Cell Lymphoma; Refractory Mantle Cell Lymphoma; Refractory Non-Hodgkin Lymphoma; Refractory Small Lymphocytic Lymphoma	Biological: Autologous Anti-CD19CAR- 4-1BB-CD3zeta-EGFRt-expressing T Lymphocytes; Other: Laboratory Biomarker Analysis	WA	NCT01865617
Cellular Immunotherapy Treatment Antigen-Directed for EBV Lymphoma	Lymphoma, Extranodal NK-T-Cell; EBV	Biological: CMD-003	CA; DC; MA; MN; NJ; NY; OH; TX	NCT01948180
Cytotoxic T Cells to Treat Relapsed EBV-positive Lymphoma	Hodgkin Disease; Non Hodgkin Lymphoma; Lymphoepithelioma; Severe Chronic Active EBV Infection Syndrome (SCAEBV); Leiomyosarcoma	Drug: LMP1/2 CTLs (Group A); Drug: LMP1/2 CTLs (Group B)	DC	NCT01956084
In Situ Vaccine for Low-Grade Lymphoma: Combination of Intratumoral Flt3L and Poly-ICLC With Low-Dose Radiotherapy	Low-Grade B-cell Lymphoma	Drug: rhuFlt3L/CDX-301; Drug: Poly-ICLC	NY	NCT01976585
A Pediatric and Young Adult Trial of Genetically Modified T Cells Directed Against CD19 for Relapsed/Refractory CD19+ Leukemia	CD19+ Acute Leukemia	Biological: Patient Derived CD19 specific CAR T cells also expressing an EGFRt	WA	NCT02028455
Memory Enriched T Cells Following Stem Cell Transplant in Treating Patients With Recurrent B-Cell Non-Hodgkin Lymphoma	Recurrent Diffuse Large B-Cell Lymphoma; Recurrent Mantle Cell Lymphoma; Refractory Diffuse Large B-Cell Lymphoma; Refractory Mantle Cell Lymphoma; Transformed Recurrent Non-Hodgkin Lymphoma	Biological: Autologous CD19CAR-CD28- CD3zeta-EGFRt-expressing Tcm-enriched T cells; Biological: Autologous CD19CAR- CD28-CD3zeta-EGFRt-expressing Tn/mem- enriched T-lymphocytes; Other: Laboratory Biomarker Analysis	CA	NCT02051257
Poly ICLC, Radiation, and Romidepsin for Advanced Cutaneous T Cell Lymphoma	Cutaneous T-cell Lymphoma	Drug: Romidepsin; Drug: Poly ICLC; Radiation: Focal lesional radiation	NY	NCT02061449
Immunotherapy Following Reduced Intensity Conditioning and Allogeneic Stem Cell Transplant for Poor Risk CD30+ Hodgkin Lymphoma Patients	Hodgkin Lymphoma	Drug: Brentuximab Vedotin; Procedure: Allogeneic Stem Cell Transplantation; Drug: Reduced Intensity Conditioning	NY	NCT02098512
A Study of ALT-803 in Patients With Relapsed or Refractory Multiple Myeloma	Relapsed or Refractory Multiple Myeloma	Biological: ALT-803	MN; M0; NY; PA	NCT02099539
A Pilot Study of Immunotherapy Including Haploidentical NK Cell Infusion Following CD133+ Positively-Selected Autologous Hematopoietic Stem Cells in Children With High Risk Solid Tumors or Lymphomas	Neuroblastoma; Lymphoma; High-risk Tumor	Device: CD133+ selected autologous stem cell infusion; Biological: IL-2; Biological: hu14.18K322A; Drug: Busulfan; Drug: Melphalan; Biological: GM-CSF; Drug: Bendamustine; Drug: Etoposide; Drug: Cytarabine; Drug: Carboplatin; Device: Haploidentical natural killer cell infusion; Biological: G-CSF; Drug: Etoposide phosphate	TN	NCT02130869

# LEUKEMIA/LYMPHOMA/MULTIPLE MYELOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Cellular Immunotherapy in Treating Patients With High-Risk Acute Lymphoblastic Leukemia	B-cell Adult Acute Lymphoblastic Leukemia; Recurrent Adult Acute Lymphoblastic Leukemia	Biological: autologous CD19CAR-CD28- CD3zeta-EGFRt-expressing Tcm-enriched T cells; Other: laboratory biomarker analysis; Biological: Autologous CD19CAR-CD28- CD3zeta-EGFRt-expressing Tn/mem- enriched T-lymphocytes	CA	NCT02146924
Genetically Modified T-cell Immunotherapy in Treating Patients With Relapsed or Refractory Acute Myeloid Leukemia	Adult Acute Myeloid Leukemia in Remission; Donor; Early Relapse of Acute Myeloid Leukemia; Late Relapse of Acute Myeloid Leukemia; Recurrent Adult Acute Myeloid Leukemia; Secondary Acute Myeloid Leukemia	Drug: cyclophosphamide; Biological: Autologous CD123CAR-CD28-CD3zeta- EGFRt-expressing T Lymphocytes; Other: laboratory biomarker analysis; Drug: Etoposide; Drug: Fludarabine Phosphate; Biological: Allogeneic CD123CAR-CD28- CD3zeta-EGFRt-expressing T-lymphocytes	CA	NCT02159495
Micro Needle Array-Doxorubicin (MNA-D) in Patients With Cutaneous T-cell Lymphoma (CTCL)	Cutaneous T Cell Lymphoma	Drug: Micro needle array-Doxorubicin (MNA-D)	PA	NCT02192021
A Study Of PF-05280586 (Rituximab-Pfizer) Or MabThera (Rituximab-EU) For The First-Line Treatment Of Patients With CD20-Positive, Low Tumor Burden, Follicular Lymphoma (REFLECTIONS B328-06)	Follicular Lymphoma	Biological: PF-05280586; Biological: MabThera	AL; AZ; CA; CO; CT; GA; IA; IL; KS; KY; MD; MO; MT; NC; NE; NV; NY; OH; OR; TN; TX; VA; WA	NCT02213263
Study of T Cells Targeting B-Cell Maturation Antigen for Previously Treated Multiple Myeloma	Myeloma, Plasma-Cell; Myeloma-Multiple	Drug: Cyclophosphamide; Drug: Fludarabine; Biological: Anti-BCMA CAR T cells	MD	NCT02215967
Immunochemotherapy and AlloSCT in Patients With High Risk CD33+ AML/MDS	Acute Myelogenous Leukemia; Myelodysplastic Syndrome	Drug: Gemtuzumab Ozogamicin	NY; WI	NCT02221310
Cord Blood Natural Killer (NK) Cells in Chronic Lymphocytic Leukemia (CLL)	Leukemia	Drug: Lenalidomide; Drug: Rituximab; Drug: Fludarabine; Drug: Cyclophosphamide; Procedure: NK Cells	TX	NCT02280525
Anti-CD22 Chimeric Receptor T Cells in Pediatric and Young Adults With Recurrent or Refractory CD22-expressing B Cell Malignancies	Follicular Lymphoma; ALL; NHL; Large Cell Lymphoma	Biological: CD22-CAR	MD	NCT02315612
Rituximab With or Without Yttrium Y-90 Ibritumomab Tiuxetan in Treating Patients With Untreated Follicular Lymphoma	Stage I Grade 1 Follicular Lymphoma; Stage I Grade 2 Follicular Lymphoma; Stage II Grade 1 Contiguous Follicular Lymphoma; Stage II Grade 1 Non-Contiguous Follicular Lymphoma; Stage II Grade 2 Contiguous Follicular Lymphoma; Stage II Grade 2 Non-Contiguous Follicular Lymphoma; Stage III Grade 1 Follicular Lymphoma; Stage III Grade 2 Follicular Lymphoma; Stage IV Grade 1 Follicular Lymphoma; Stage IV Grade 2 Follicular Lymphoma; Stage IV Grade 2 Follicular Lymphoma	Other: Laboratory Biomarker Analysis; Other: Quality-of-Life Assessment; Biological: Rituximab; Radiation: Yttrium Y-90 Ibritumomab Tiuxetan	IA; MN	NCT02320292
PK, PD, Safety, Tolerability of Multiple Dose Regimens of MT-3724 for the Treatment of Patients With Relapsed Non-Hodgkin's B-Cell Lymphoma and B-Cell Chronic Lymphocytic Leukemia	Non-Hodgkin's B-cell Lymphoma; Leukemia, Lymphocytic, Chronic, B-Cell; Small Lymphocytic Leukemia	Drug: MT-3724	AZ; NC; NY; TX	NCT02361346
Safety Study of SEA-CD40 in Cancer Patients	Cancer; Carcinoma; Neoplasms; Neoplasm Metastasis; Hematologic Malignancies; Hodgkin Disease; Lymphoma; Lymphoma, B-Cell; Lymphoma, Follicular; Lymphoma, Large B-Cell, Diffuse; Lymphoma, Non-Hodgkin	Drug: SEA-CD40	IL; MI; NC; NY; OR; WA	NCT02376699
ALT-803 in Patients With Relapse/Refractory Indolent B Cell Non-Hodgkin Lymphoma (iNHL) in Conjunction With Rituximab	Relapsed/Refractory Indolent B Cell Non- Hodgkin Lymphoma	Biological: Rituximab; Biological: ALT-803	MO	NCT02384954
Pilot Project for Creation of the Diffuse Large B-cell Lymphoma (DLBCL) Response Prediction Model	Lymphoma	Drug: 18F-fluorodeoxyglucose; Procedure: FDG PET/CT Imaging; Procedure: Blood Draws	TX	NCT02405078
IPA Targeted Adoptive Immunotherapy vs Adult Haplo- identical Cell Infusion During Induction of High Risk Leukemia	Acute Myeloid Leukemia; Myelodysplastic Syndrome	Biological: haplo-identical cells (donor); Biological: umbilical cord blood unit (CBU)	NY	NCT02508324
Study of Pembrolizumab in Combination With Ublituximab and TGR-1202 in Patients With Relapsed-refractory CLL	Chronic Lymphocytic Leukemia	Drug: Pembrolizumab; Drug: TGR-1202; Biological: ublituximab	PA	NCT02535286
NM-IL-12 in Cutaneous T-Cell Lymphoma (CTCL) Undergoing Total Skin Electron Beam Therapy (TSEBT)	Cutaneous T Cell Lymphoma (CTCL); Mycosis Fungoides; Sézary Syndrome	Biological: NM-IL-12	CA; CT; NY; PA	NCT02542124
MEDI4736 Alone and in Combination With Tremelimumab or AZD9150 in Adult Subjects With Diffuse Large B-cell Lymphoma (D4190C00023)	Diffuse Large B-Cell Lymphoma	Drug: MEDI4736; Drug: tremelimumab; Drug: AZD9150	IL; TX	NCT02549651
A Study of Brentuximab Vedotin Combined With Nivolumab for Relapsed or Refractory Hodgkin Lymphoma	Hodgkin Lymphoma	Drug: brentuximab vedotin; Drug: nivolumab	CA; MA; MI; MN; MO; NC; NE; NJ; NY; OH; TX	NCT02572167
Treatment Study of Denintuzumab Mafodotin (SGN-CD19A) Plus RICE Versus RICE Alone for Diffuse Large B-Cell Lymphoma	Lymphoma, B-cell; Lymphoma, Large B-Cell, Diffuse; Lymphoma, Follicular, Grade 3b; Follicular Lymphoma, Grade 3b	Drug: denintuzumab mafodotin; Drug: rituximab; Drug: ifosfamide; Drug: carboplatin; Drug: etoposide	AR; CA; FL; IL; MN; M0; NC; NJ; NY; TX; VA; WA; WI	NCT02592876

# LEUKEMIA/LYMPHOMA/MULTIPLE MYELOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Allogeneic Stem Cell Transplantationin Relapsed Hematological Malignancy: Early GVHD Prophylaxis	Hodgkin's Lymphoma; Lymphoid Leukemia; Lymphoma; Leukemia; Myeloma	Drug: mycophenolate mofetil; Drug: Tacrolimus; Biological: Sargramostim; Biological: Filgrastim; Drug: Antithymocyte Globulin (Rabbit)	VA	NCT02593123
Pembrolizumab in Treating Patients With HIV and Relapsed, Refractory, or Disseminated Malignant Neoplasms	AIDS-Related Non-Hodgkin Lymphoma; Classical Hodgkin Lymphoma; HIV Infection; Locally Advanced Malignant Neoplasm; Metastatic Malignant Neoplasm; Recurrent Hepatocellular Carcinoma; Recurrent Hodgkin Lymphoma; Recurrent Kaposi Sarcoma; Recurrent Malignant Neoplasm; Recurrent Melanoma of the Skin; Recurrent Non-Hodgkin Lymphoma; Recurrent Non-Small Cell Lung Carcinoma; Refractory Hodgkin Lymphoma; Refractory Malignant Neoplasm; Solid Neoplasm; Stage IIIA Non-Small Cell Lung Carcinoma; Stage IIIA Non-Small Cell Lung Cancer; Stage IIIA Non-Small Cell Lung Cancer; Stage IIIB Skin Melanoma; Stage IIIC Skin Melanoma; Stage IV Skin Melanoma; Stage IVA Hepatocellular Carcinoma; Stage IVA Hepatocellular Carcinoma; Stage IVB Hepatocellular Carcinoma; Stage IVB Hepatocellular Carcinoma;	Other: Laboratory Biomarker Analysis; Biological: Pembrolizumab	MD; WA	NCT02595866
Study of Copanlisib in Combination With Standard Immunochemotherapy in Relapsed Indolent Non-Hodgkin's Lymphoma (iNHL)	Lymphoma, Non-Hodgkin	Drug: Copanlisib (BAY 80-6946); Drug: Placebo; Drug: Rituximab; Drug: Cyclophosphamide; Drug: Doxorubicin; Drug: Vincristine; Drug: Bendamustine; Drug: Prednisone	NJ; NY; OH	NCT02626455
Samples From Leukemia Patients and Their Donors to Identify Specific Antigens	Leukemia		CA	NCT02667093
Biospecimen Procurement for Experimental Transplantation and Immunology Branch Immunotherapy Protocols	Multiple Myeloma; Lymphoma, Non-Hodgkin; Leukemia-Lymphoma, Adult T-Cell; Hodgkin Disease; Non-Small Cell Lung Cancer		MD	NCT02682667
JCAR014 and Durvalumab in Treating Patients With Relapsed or Refractory B-cell Non-Hodgkin Lymphoma	Diffuse Large B-Cell Lymphoma, Not Otherwise Specified; Recurrent Diffuse Large B-Cell Lymphoma; Recurrent Mediastinal (Thymic) Large B-Cell Cell Lymphoma; Refractory Diffuse Large B-Cell Lymphoma; Refractory Mediastinal (Thymic) Large B-Cell Cell Lymphoma	Biological: JCAR014; Drug: Cyclophosphamide; Biological: Durvalumab; Drug: Fludarabine Phosphate; Other: Pharmacological Study	WA	NCT02706405
Extended Treatment Access Study of MT-3724 for Subjects With Relapsed Non-Hodgkin's B-Cell Lymphoma	Non-Hodgkin's B-cell Lymphoma	Drug: MT-3724	AZ; NC; NY; TX	NCT02715843
Cellular Immunotherapy for Viral Induced Cancer	Hodgkin Lymphoma; Lymphoma, Large B-Cell, Diffuse; Post-transplant Lymphoproliferative Disorder	Biological: CMD-003	CA; DC; IL; MA; MD; MN; NY; OH; PA; TX	NCT02763254
Vadastuximab Talirine (SGN-CD33A; 33A) Combined With Azacitidine or Decitabine in Older Patients With Newly Diagnosed Acute Myeloid Leukemia	Acute Myeloid Leukemia	Drug: 33A; Drug: placebo; Drug: azacitidine; Drug: decitabine	CA; CO; FL; KY; MA; MD; MO; NJ; NY; OR; SC; TN; UT; VA; WA	NCT02785900
Durvalumab in Pediatric and Adolescent Patients	Solid Tumors ,; Lymphoma; Central Nervous System Tumors	Drug: Durvalumab; MEDI4736	CA	NCT02793466
DA-EPOCH-Rituximab/Metformin (RM) for Double Hit Lymphoma	Diffuse Large B-Cell Lymphoma	Drug: Metformin	IL	NCT02815397
Denintuzumab Mafodotin (SGN-CD19A) Combined With RCHOP or RCHP Versus RCHOP Alone in Diffuse Large B-Cell Lymphoma or Follicular Lymphoma	Diffuse, Large B-Cell, Lymphoma; Follicular Lymphoma, Grade 3b; Transformed Lymphoma / DLBCL	Drug: denintuzumab mafodotin; Drug: rituximab; Drug: cyclophosphamide; Drug: doxorubicin; Drug: vincristine; Drug: prednisone	MN; MS; NM; OH; WA	NCT02855359
Multi-Dose CD30 CAR T Cells, Relapsed CD30 Expressing Lymphoma (RELY-30)	Hodgkin's Lymphoma; Non-Hodgkin Lymphoma	Genetic: CAR T Cells; Drug: Cyclophosphamide; Drug: Fludarabine	TX	NCT02917083

# LIVER

Title	Cancer Type	Treatment	Location	NCT Number
T Cell Receptor Immunotherapy Targeting NY-ESO-1 for Patients With NY-ESO-1 Expressing Cancer	Synovial Sarcoma; Breast Cancer; Non-Small Cell Lung Cancer; Hepatocellular Cancer	Biological: Anti-NY ESO-1 mTCR PBL; Drug: Cyclophosphamide; Drug: Fludarabine; Drug: Aldesleukin	MD	NCT01967823
Ipilimumab and Stereotactic Body Radiation Therapy (SBRT) in Advanced Solid Tumors	Liver Cancer; Lung Cancer	Drug: Ipilimumab; Radiation: Stereotactic Body Radiation Therapy (SBRT)	TX	NCT02239900
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer; Head and Neck Squamous Cell Cancer; Ovarian Cancer; Colorectal Cancer; Gastric Cancer; Esophageal Cancer; Hepatocellular Cancer	Biological: INO-1400; Biological: INO-9012	MI; NC; PA	NCT02327468
A Study of MEDI4736 With Tremelimumab, MEDI4736 or Tremelimumab Monotherapy in Unresectable Hepatocellular Carcinoma	Hepatocellular Carcinoma	Biological: MEDI4736 + tremelimumab; Biological: MEDI4736; Biological: Tremelimumab	AZ; CA; CT; FL; IN; MA; NC; NY; OR; PA; TN; TX	NCT02519348

# LIVER (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Hepatocellular Carcinoma Study Comparing Vaccinia Virus Based Immunotherapy Plus Sorafenib vs Sorafenib Alone	Hepatocellular Carcinoma (HCC)	Biological: Pexastimogene Devacirepvec (Pexa Vec); Drug: Sorafenib	CA; FL; IL; MD; MO; MT; NJ; TN; WA	NCT02562755
Pembrolizumab in Treating Patients With HIV and Relapsed, Refractory, or Disseminated Malignant Neoplasms	AIDS-Related Non-Hodgkin Lymphoma; Classical Hodgkin Lymphoma; HIV Infection; Locally Advanced Malignant Neoplasm; Metastatic Malignant Neoplasm; Recurrent Hepatocellular Carcinoma; Recurrent Hodgkin Lymphoma; Recurrent Kaposi Sarcoma; Recurrent Malignant Neoplasm; Recurrent Melanoma of the Skin; Recurrent Non- Hodgkin Lymphoma; Refractory Hodgkin Lymphoma; Refractory Hodgkin Lymphoma; Refractory Malignant Neoplasm; Solid Neoplasm; Stage IIIA Hepatocellular Carcinoma; Stage IIIA Non-Small Cell Lung Cancer; Stage IIIA Skin Melanoma; Stage IIIB Hepatocellular Carcinoma; Stage IIIB Non-Small Cell Lung Cancer; Stage IIIB Skin Melanoma; Stage IIIC Hepatocellular Carcinoma; Stage IIIC Hepatocellular Carcinoma; Stage IIL Ung Cancer; Stage IV Non-Small Cell Lung Cancer; Stage IV Skin Melanoma; Stage IVA Hepatocellular Carcinoma; Stage IVB Hepatocellular Carcinoma; Stage IVB Hepatocellular	Other: Laboratory Biomarker Analysis; Biological: Pembrolizumab	MD; WA	NCT02595866
Study of Nivolumab in Patients With Advanced Refractory Biliary Tract Cancers	Biliary Tract Cancer; Biliary Tract Neoplasms	Drug: Nivolumab	FL	NCT02829918
CAR-T Hepatic Artery Infusions for CEA-Expressing Liver Metastases	Liver Metastases	Biological: anti-CEA CAR-T cells	RI	NCT02850536
Glypican 3-specific Chimeric Antigen Receptor Expressing T Cells for Hepatocellular Carcinoma (GLYCAR)	Hepatocellular Carcinoma	Genetic: GLYCAR T cells; Drug: Cytoxan; Drug: Fludarabine	TX	NCT02905188

# LUNG

Title	Cancer Type	Treatment	Location	NCT Number
Evaluation for NCI Surgery Branch Clinical Studies	Synovial Cell Cancer; Melanoma; Colorectal Cancer; Lung Cancer; Bladder Cancer		MD	NCT00001823
CAR T Cell Receptor Immunotherapy Targeting Mesothelin for Patients With Metastatic Cancer	Cervical Cancer; Pancreatic Cancer; Ovarian Cancer; Mesothelioma; Lung Cancer	Drug: Fludarabine; Biological: Anti- mesothelin CAR; Drug: Cycolphosphamide; Drug: Aldesleukin	MD	NCT01583686
Combination Vaccine Immunotherapy (DRibbles) for Patients With Definitively-Treated Stage III Non-small Cell Lung Cancer	Carcinoma, Non-Small-Cell Lung	Drug: Cyclophosphamide; Biological: DRibble vaccine; Drug: Imiquimod; Drug: GM-CSF; Biological: HPV vaccine	LA; OR	NCT01909752
T Cell Receptor Immunotherapy Targeting NY-ESO-1 for Patients With NY-ESO-1 Expressing Cancer	Synovial Sarcoma; Breast Cancer; Non-Small Cell Lung Cancer; Hepatocellular Cancer	Biological: Anti-NY ESO-1 mTCR PBL; Drug: Cyclophosphamide; Drug: Fludarabine; Drug: Aldesleukin	MD	NCT01967823
A Phase 1b Study of MEDI4736 in Combination With Tremelimumab in Subjects With Advanced Non-small Cell Lung Cancer	NSCLC; Non-small Cell Lung Cancer; Lung Cancer	Drug: MEDI4736; Drug: Tremelimumab; Drug: MEDI4736; Drug: MEDI4736; Drug: MEDI4736; Drug: Tremelimumab; Drug: tremelimumab; Drug: tremelimumab	AL; AZ; CA; CO; CT; DE; FL; IN; MA; MD; MI; MO; NC; NH; NY; OH; OR; PA; SC; TX; VA; WA; WV	NCT02000947
A Phase 1 Study of AM0010 in Patients With Advanced Solid Tumors	Melanoma; Prostate Cancer; Ovarian Cancer; Renal Cell Carcinoma; Colorectal Carcinoma; Pancreatic Carcinoma; Non-small Cell Lung Carcinoma; Solid Tumors; Breast Cancer	Drug: AM0010; Drug: Paclitaxel or Docetaxel and Carboplatin or Cisplatin; Drug: FOLFOX (Oxaliplatin/Leucovorin/5- Fluorouracil); Drug: gemcitabine/ nab-paclitaxel; Drug: Capecitabine; Drug: Pazopanib; Drug: Pembrolizumab; Drug: Paclitaxel; Drug: nivolumab; Drug: Gemcitabine/carboplatin	CA; CO; FL; MA; NY; OK; TN; TX	NCT02009449
A Study of Pembrolizumab (MK-3475) in Combination With Chemotherapy or Immunotherapy in Participants With Lung Cancer (MK-3475-021/KEYNOTE-021)	Non-small Cell Lung Carcinoma	Biological: Pembrolizumab; Drug: Paclitaxel; Drug: Carboplatin; Biological: Bevacizumab; Drug: Pemetrexed; Biological: Ipilimumab; Drug: Erlotinib; Drug: Gefitinib	CA; IN; MA; NC; NE; NJ; NY; OH; PA; TX; WA	NCT02039674
T Cell Receptor Immunotherapy for Patients With Metastatic Non-Small Cell Lung Cancer	Metastatic Non-Small Cell Lung Cancer; Squamous Cell Carcinoma; Advanced NSCLC; Adenosquamous Carcinoma; Adenocarcinomas	Drug: Aldesleukin; Drug: Fludarabine; Drug: Cyclophosphamide; Biological: Young TIL	MD	NCT02133196
Ipilimumab and Stereotactic Body Radiation Therapy (SBRT) in Advanced Solid Tumors	Liver Cancer; Lung Cancer	Drug: Ipilimumab; Radiation: Stereotactic Body Radiation Therapy (SBRT)	TX	NCT02239900
Safety and Efficacy Study of Nab-Paclitaxel With CC-486 or Nab-Paclitaxel With Durvalumab, and Nab-Paclitaxel Monotherapy as Second/Third-line Treatment for Advanced Non-small Cell Lung Cancer	Carcinoma, Non-Small-Cell Lung	Drug: nab-paclitaxel IV; Drug: CC-486; Drug: Duravalumab	CA; CT; GA; MO; NJ; NY; PA; TN; TX	NCT02250326

# **LUNG** (CONTINUED)

LUNG (CONTINUED)				
Title	Cancer Type	Treatment	Location	NCT Number
Double Blind Placebo Controlled Controlled Study of Adjuvant MEDI4736 In Completely Resected NSCLC	Non-Small Cell Lung Cancer	Drug: MEDI4736; Drug: Placebo	CA; CO; FL; NC; PA	NCT02273375
Trial of Active Immunotherapy With OBI-833 (Globo H-CRM197)in Gastric, Lung, Colorectal or Breast Cancer Subjects	Metastatic Gastric Cancer; Metastatic Breast Cancer; Metastatic Colorectal Cancer; Metastatic Lung Cancer	Drug: OBI-833/OBI-821	OH; TX	NCT02310464
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer; Head and Neck Squamous Cell Cancer; Ovarian Cancer; Colorectal Cancer; Gastric Cancer; Esophageal Cancer; Hepatocellular Cancer	Biological: INO-1400; Biological: INO-9012	MI; NC; PA	NCT02327468
Trial of PBF-509 and PDR001 in Patients With Advanced Non-small Cell Lung Cancer (NSCLC)	Non-small Cell Lung Cancer (NSCLC)	Drug: PBF-509_80 mg; Drug: PBF-509_160 mg; Drug: PBF-509_320 mg; Drug: PBF-509_640 mg; Drug: Combo PBF-509 (160 mg) + PDR001; Drug: Combo PBF-509 (320 mg) + PDR001; Drug: Combo PBF-509 (640 mg) + PDR001; Drug: RP2D (PBF-509+PDR001)_immuno naive; Drug: Experimental: RP2D (PBF-509+PDR001)_immuno treated	FL .	NCT02403193
A Multi-Center Study of Ibrutinib in Combination With MEDI4736 in Subjects With Relapsed or Refractory Solid Tumors	Non-Small Cell Lung Cancer	Drug: Ibrutinib; Drug: Durvalumab (MEDI4736)	AL; AZ; CA; FL; IL; NC; NJ; TN; TX	NCT02403271
Genetically Modified T Cells in Treating Patients With Stage III-IV Non-small Cell Lung Cancer or Mesothelioma	Advanced Pleural Malignant Mesothelioma; HLA-A*0201 Positive Cells Present; Recurrent Non-Small Cell Lung Carcinoma; Recurrent Pleural Malignant Mesothelioma; Stage III Pleural Mesothelioma; Stage IIIA Non-Small Cell Lung Cancer; Stage IIB Non-Small Cell Lung Cancer; Stage IV Non-Small Cell Lung Cancer; Stage IV Pleural Mesothelioma	Biological: Aldesleukin; Biological: Autologous WT1-TCRc4 Gene-transduced CD8-positive Tcm/Tn Lymphocytes; Drug: Cyclophosphamide; Other: Laboratory Biomarker Analysis; Procedure: Therapeutic Conventional Surgery	WA	NCT02408016
Malignant Pleural Disease Treated With Autologous T Cells Genetically Engineered to Target the Cancer-Cell Surface Antigen Mesothelin	Malignant Pleural Disease; Mesothelioma; Metastases; Lung Cancer; Breast Cancer	Genetic: iCasp9M28z T cell infusions; Drug: cyclophosphamide	NY	NCT02414269
MK-3475 and Gemcitabine in Non-Small Cell Lung Cancer (NSCLC)	Carcinoma, Non-Small-Cell Lung	Drug: MK-3475; Drug: Gemcitabine	OR	NCT02422381
A Study of Combination Therapies With Viagenpumatucel-L (HS-110) in Patients With Non-Small Cell Lung Cancer	Non-small Cell Lung Cancer	Biological: Viagenpumatucel-L; Drug: Nivolumab	AL; IN; KY; MO; OH	NCT02439450
Immunotherapy Combination Study in Advanced Previously Treated Non-Small Cell Lung Cancer	Non-small Cell Lung Cancer; Progression of Non-small Cell Lung Cancer; Non-small Cell Lung Cancer Recurrent	Drug: Docetaxel; Biological: Tergenpumatucel-L; Drug: Indoximod 600mg; Drug: Indoximod 1200mg	MO	NCT02460367
A Pilot Study of MPDL3280A and HIGRT in Metastatic NSCLC	Non-small Cell Lung Cancer	Drug: MPDL3280A; Radiation: Hypofractionated Radiotherapy	MI; WA	NCT02463994
Study of Nivolumab in Combination With GM.CD40L Vaccine in Adenocarcinoma of the Lung	Lung Cancer; Adenocarcinoma of the Lung	Drug: Nivolumab; Biological: GM.CD40L Vaccine	FL	NCT02466568
Safety & Immunogenicity of JNJ-64041757, Live-attenuated Double-deleted Listeria Immunotherapy, in Subjects With Non Small Cell Lung Cancer	Carcinoma, Non-Small-Cell Lung	Biological: JNJ-64041757 (Cohort 1A and 1B); Biological: JNJ-64041757 (Cohort 2A and 2B)	CA; MA; MD; MI; MO; PA; TN; TX	NCT02592967
Pembrolizumab in Treating Patients With HIV and Relapsed, Refractory, or Disseminated Malignant Neoplasms	AIDS-Related Non-Hodgkin Lymphoma; Classical Hodgkin Lymphoma; HIV Infection; Locally Advanced Malignant Neoplasm; Metastatic Malignant Neoplasm; Recurrent Hepatocellular Carcinoma; Recurrent Hodgkin Lymphoma; Recurrent Kaposi Sarcoma; Recurrent Malignant Neoplasm; Recurrent Melanoma of the Skin; Recurrent Non-Small Cell Lung Carcinoma; Refractory Hodgkin Lymphoma; Refractory Malignant Neoplasm; Solid Neoplasm; Stage IIIA Non-Small Cell Lung Carcinoma; Stage IIIA Non-Small Cell Lung Cancer; Stage IIIA Non-Small Cell Lung Cancer; Stage IIIA Skin Melanoma; Stage IIIB Non-Small Cell Lung Cancer; Stage IIIB Skin Melanoma; Stage IIIC Hepatocellular Carcinoma; Stage IIIC Skin Melanoma; Stage IV Non-Small Cell Lung Cancer; Stage IV Skin Melanoma; Stage IVB Hepatocellular Carcinoma; Stage IVB Hepatocellular Carcinoma; Stage IVB Hepatocellular Carcinoma;	Other: Laboratory Biomarker Analysis; Biological: Pembrolizumab	MD; WA	NCT02595866
Serial [18F]Fluorodeoxyglucose ([18F]FDG )PET/CT as a Biomarker of Therapeutic Response in Anti-PD1/PDL1 Therapy	Non-Small Cell Lung Cancer (NSCLC)	Radiation: [18F]fluoroglucose(FDG)	PA	NCT02608528
Vigil + Nivolumab in Advanced Non-Small Cell Lung Cancer	Advanced Non-small Cell Lung Cancer; Metastatic Non-small Cell Lung Cancer; Lung Neoplasms	Biological: Vigil; Drug: Nivolumab	TX; WA	NCT02639234
Study of OSE2101 Versus Standard Treatment as 2nd or 3rd Line in HLA-A2 Positive Patients With Advanced NSCLC	Non Small Cell Lung Cancer	Drug: OSE2101; Drug: Docetaxel; Drug: Pemetrexed	AR; DC; LA; MS; NJ; OH; OK; PA; TX	NCT02654587

# **LUNG** (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
A Safety and Feasibility Study of AGS-003-LNG for the Treatment of Stage 3 Non Small Cell Lung Cancer	Non-small Cell Lung Cancer (NSCLC)	Biological: AGS-003-LNG; Drug: Carboplatin; Drug: Abraxane; Drug: Alimta; Drug: Cisplatin; Drug: Taxol; Radiation: Radiation Therapy	NE	NCT02662634
Phase II Trial of Sequential Consolidation With Pembrolizumab Followed by Nab-paclitaxel	Non Small Cell Lung Cancer	Drug: Pembrolizumab	NC	NCT02684461
Cisplatin and Etoposide Plus Radiation Followed By Nivolumab/Placebo For Locally Advanced NSCLC	Non-Small Cell Lung Cancer	Radiation: Thoracic RT; Drug: Cisplatin; Drug: Etoposide; Drug: Nivolumab; Other: Placebo	NY	NCT02768558
Oncology Research Information Exchange Network (ORIEN) Lung Cancer Study	Lung Cancer; Non-small Cell Lung Cancer	Other: No Intervention	FL	NCT02803333
Trial of Stereotactic Body Radiation and Gene Therapy Before Nivolumab for Metastatic Non-Small Cell Lung Carcinoma	Lung Squamous Cell Carcinoma Stage IV; Nonsquamous Nonsmall Cell Neoplasm of Lung	Biological: ADV/HSV-tk; Drug: Valacyclovir; Radiation: SBRT; Drug: nivolumab	TX	NCT02831933
FLT3 Ligand Immunotherapy and Stereotactic Radiotherapy for Advanced Non-small Cell Lung Cancer	Non-small Cell Lung Cancer (NSCLC)	Drug: FLT3 Ligand Therapy (CDX-301); Radiation: Stereotactic Body Radiotherapy (SBRT)	NY	NCT02839265
Anti-Mesothelin Antibody Drug Conjugate Anetumab Ravtansine for Mesothelin Expressing Lung Adenocarcinoma	Lung Neoplasms	Drug: Anetumab Ravtansine	MD	NCT02839681
Evaluation of Tumor and Blood Immune Biomarkers in Resected Non-small Cell Lung Cancer	Non-small Cell Lung Carcinoma		NC	NCT02848872
A Personalized Cancer Vaccine (NEO-PV-01) w/ Nivolumab for Patients With Melanoma, Lung Cancer or Bladder Cancer	Urinary Bladder Cancer; Bladder Tumors; Transitional Cell Carcinoma of the Bladder; Malignant Melanoma; Melanoma; Skin Cancer; Carcinoma, Non-Small-Cell Lung; Lung Cancer	Biological: NEO-PV-01; Biological: Nivolumab; Other: Adjuvant	CA; MA; TX	NCT02897765
Bronchoscopy With Bronchoalveolar Lavage in Identifying Biomarkers of Response to Immune Checkpoint Inhibitors in Patients With Non-small Cell or Small Cell Lung Cancer	Non-Small Cell Lung Carcinoma; Small Cell Lung Carcinoma	Procedure: Bronchoscopy with Bronchoalveolar Lavage; Other: Laboratory Biomarker Analysis	TN	NCT02937402
Targeted Therapy in Treating Patients With Incurable Non- Small Cell Lung Cancer With Genetic Mutations	EGFR Activating Mutation; Recurrent Non-Small Cell Lung Carcinoma; Stage IV Non-Small Cell Lung Cancer	Drug: Chemotherapy, Biological: Immunotherapy, Other: Laboratory Biomarker Analysis; Biological: Nivolumab; Biological: Pembrolizumab; Drug: Targeted Molecular Therapy; Drug: Tyrosine Kinase Inhibitor	NC	NCT02949843

#### **MELANOMA**

WELLANOWA				
Title	Cancer Type	Treatment	Location	NCT Number
Evaluation for NCI Surgery Branch Clinical Studies	Synovial Cell Cancer; Melanoma; Colorectal Cancer; Lung Cancer; Bladder Cancer		MD	NCT00001823
Comparison of High-dose IL-2 and High-dose IL-2 With Radiation Therapy in Patients With Metastatic Melanoma.	Metastatic Melanoma	Other: Radiation therapy and high-dose IL-2; Drug: High-dose IL-2	OR	NCT01416831
Vemurafenib With Lymphodepletion Plus Adoptive Cell Transfer & High Dose IL-2 Metastatic Melanoma	Metastatic Melanoma	Drug: High Dose Interleukin-2 (IL-2); Procedure: ACT with TIL Infusion; Drug: Vemurafenib; Drug: Lymphodepletion	FL	NCT01659151
Dendritic Cell Activating Scaffold in Melanoma	Melanoma	Biological: WDVAX	MA	NCT01753089
Tumor-Infiltrating Lymphocytes After Combination Chemotherapy in Treating Patients With Metastatic Melanoma	Stage IIIA Skin Melanoma; Stage IIIB Skin Melanoma; Stage IIIC Skin Melanoma; Stage IV Skin Melanoma	Biological: Aldesleukin; Drug: Cyclophosphamide; Drug: Fludarabine Phosphate; Other: Laboratory Biomarker Analysis; Biological: Therapeutic Tumor Infiltrating Lymphocytes	WA	NCT01807182
The Effects of Vemurafenib + Cobimetinib on Immunity in Patients With Melanoma	Melanoma	Drug: Vemurafenib	DC; MA; TX; VA	NCT01813214
Immunotherapy Using Tumor Infiltrating Lymphocytes for Patients With Metastatic Ocular Melanoma	Metastatic Ocular Melanoma; Metastatic Uveal Melanoma	Drug: Aldesleukin; Drug: Cyclophosphamide; Drug: Fludarabine; Biological: Young TIL	MD	NCT01814046
Dendritic Cell Vaccines + Dasatinib for Metastatic Melanoma	Metastatic Melanoma	Biological: DC vaccine; Drug: Dasatinib	PA	NCT01876212
Epacadostat and Vaccine Therapy in Treating Patients With Stage III-IV Melanoma	Mucosal Melanoma; Recurrent Melanoma; Recurrent Uveal Melanoma; Stage IIIA Skin Melanoma; Stage IIIA Uveal Melanoma; Stage IIIB Skin Melanoma; Stage IIIB Uveal Melanoma; Stage IIIC Skin Melanoma; Stage IIIC Uveal Melanoma; Stage IV Skin Melanoma; Stage IV Uveal Melanoma	Drug: Epacadostat; Other: Laboratory Biomarker Analysis; Biological: MELITAC 12.1 Peptide Vaccine	GA; NC; NH; OH; VA	NCT01961115

# MELANOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Immunotherapy Using Tumor Infiltrating Lymphocytes for Patients With Metastatic Melanoma	Metastatic Melanoma	Drug: Aldesleukin; Drug: Fludarabine; Drug: Cyclophosphamide; Biological: Young Tumor Infiltrating Lymphocytes (Young TIL); Drug: Keytruda (pembrolizumab) - ONLY FOR RETREATMENT	MD	NCT01993719
A Phase 1 Study of AM0010 in Patients With Advanced Solid Tumors	Melanoma; Prostate Cancer; Ovarian Cancer; Renal Cell Carcinoma; Colorectal Carcinoma; Pancreatic Carcinoma; Non-small Cell Lung Carcinoma; Solid Tumors; Breast Cancer	Drug: AM0010; Drug: Paclitaxel or Docetaxel and Carboplatin or Cisplatin; Drug: FOLFOX (Oxaliplatin/Leucovorin/5-Fluorouracil); Drug: gemcitabine/ nab-paclitaxel; Drug: Capecitabine; Drug: Pazopanib; Drug: Pembrolizumab; Drug: Paclitaxel; Drug: nivolumab; Drug: Gemcitabine/carboplatin	CA; CO; FL; MA; NY; OK; TN; TX	NCT02009449
Cellular Adoptive Immunotherapy Using Autologous CD8+ Antigen-Specific T Cells and Anti-CTLA4	Melanoma	Drug: Cyclophosphamide; Procedure: CD8+ T Cells; Drug: Interleukin-2; Drug: Ipilimumab	TX	NCT02027935
Immunotherapy Study for Patients With Stage IV Melanoma	Stage IV Melanoma; Metastatic Melanoma	Drug: HyperAcute-Melanoma (HAM) Immunotherapy; Drug: Ipilimumab; Drug: Pembrolizumab; Drug: Nivolumab	IA; IL; NC; TN	NCT02054520
Study of IDO Inhibitor in Combination With Checkpoint Inhibitors for Adult Patients With Metastatic Melanoma	Metastatic Melanoma; Stage III Melanoma; Stage IV Melanoma	Drug: Indoximod; Drug: Ipilimumab; Drug: Nivolumab; Drug: Pembrolizumab	GA; IA; MN; NM; PA; UT	NCT02073123
Molecularly Targeted Therapy in Treating Patients With BRAF Wild-type Melanoma That is Metastatic	Recurrent Melanoma; Stage IIIA Melanoma; Stage IIIB Melanoma; Stage IIIC Melanoma; Stage IV Melanoma	Other: cytology specimen collection procedure; Drug: MEK 162 therapy or molecularly targeted therapy; Procedure: therapeutic procedure; Other: laboratory biomarker analysis; Other: quality-of-life assessment	AZ; CT; FL; IN; MD; MI; MN; TN; TX	NCT02094872
A Phase I Trial of T Cells Expressing an Anti-GD2 Chimeric Antigen Receptor in Children and Young Adults With GD2+ Solid Tumors	Sarcoma; Osteosarcoma; Neuroblastoma; Melanoma	Biological: Anti-GD2-CAR engineered T cells; Drug: AP1903; Drug: Cyclophosphamide	MD	NCT02107963
Galectin Inhibitor (GR-MD-02) and Ipilimumab in Patients With Metastatic Melanoma	Metastatic Melanoma	Biological: 1 mg/kg GR-MD-02; Biological: 2 mg/kg GR-MD-02; Biological: 4 mg/kg GR-MD-02; Biological: 8 mg/kg GR-MD-02; Biological: Ipilimumab	OR	NCT02117362
Phase 1 Study of Intradermal LV305 in Patients With Locally Advanced, Relapsed or Metastatic Cancer Expressing NY-ESO-1	Melanoma - Currently Enrolling; Non-small Cell Lung Cancer - Enrollment Completed; Ovarian Cancer - Enrollment Completed; Sarcoma - Enrollment Completed	Biological: ID-LV305	CA; CT; MA; MN; NJ; SC; TX; WA	NCT02122861
Adoptive Therapy Using Antigen-Specific CD4 T-Cells	Melanoma; Sarcoma	Drug: Ipilimumab; Drug: Cyclophosphamide; Biological: CD4+ T cells	TX	NCT02210104
Dabrafenib and Trametinib Followed by Ipilimumab and Nivolumab or Ipilimumab and Nivolumab Followed by Dabrafenib and Trametinib in Treating Patients With Stage III-IV BRAFV600 Melanoma	Recurrent Melanoma; Stage IIIA Skin Melanoma; Stage IIIB Skin Melanoma; Stage IIIC Skin Melanoma; Stage IV Skin Melanoma	Drug: Dabrafenib; Biological: Ipilimumab; Other: Laboratory Biomarker Analysis; Biological: Nivolumab; Other: Quality-of- Life Assessment; Drug: Trametinib	AK; AL; AR; CA; CO; CT; DC; DE; FL; GA; HI; IA; ID; IL; IN; KS; KY; LA; MD; MI; MN; MO; MS; MT; NC; ND; NE; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; VA; WA; WI; WV	NCT02224781
RTA 408 Capsules in Patients With Melanoma - REVEAL	Melanoma; Unresectable (Stage III) Melanoma; Metastatic (Stage IV) Melanoma	Drug: Omaveloxolone Capsules (2.5 mg/ capsule); Drug: Ipilimumab (3 mg/kg); Drug: Nivolumab (3 mg/kg)	AL; AR; CO; DC; DE; FL; MA; NC; NJ; TX	NCT02259231
Neoadjuvant Pembrolizumab for Unresectable Stage III and Unresectable Stage IV Melanoma	Unresectable Malignant Neoplasm; Melanoma; Metastatic Melanoma; Stage IV Melanoma; Stage III Melanoma	Drug: Pembrolizumab	MO	NCT02306850
A Comparison of Matured Dendritic Cells and Montanide in Study Subjects With High Risk of Melanoma Recurrence	Melanoma	Biological: DC Vaccine; Biological: Montanide Vaccine; Biological: Poly-ICLC	NY	NCT02334735
In Situ, Autologous Therapeutic Vaccination Against Solid Cancers With Intratumoral Hiltonol	Melanoma; Head and Neck Cancer; Sarcoma; Non-Melanoma Skin Cancers	Biological: Hiltonol	GA; MD; NY; PA	NCT02423863
Trial of Vemurafenib and Cobimetinib in Patients With Advanced BRAFV600 Mutant Melanoma	Melanoma	Drug: Cobimetinib; Drug: Vemurafenib	MD	NCT02427893
A Pilot Study to Evaluate PBR PET in Brain Tumor Patients Treated With Chemoradiation or Immunotherapy	Intracranial Tumors; Glioblastoma; Melanoma	Other: PBR PET; Biological: Cancer Immunotherapy; Radiation: Radiation and chemotherapy	MA	NCT02431572
Pilot Study of Vigil + Pembrolizumab for Advanced Melanoma	Melanoma Recurrent; Malignant Melanoma; Melanoma	Biological: Vigil; Drug: Pembrolizumab	TX; WA	NCT02574533
GR-MD-02 Plus Pembrolizumab in Melanoma Patients	Melanoma	Drug: GR-MD-02; Drug: Pembrolizumab	OR	NCT02575404

# MELANOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Pembrolizumab in Treating Patients With HIV and Relapsed, Refractory, or Disseminated Malignant Neoplasms	AIDS-Related Non-Hodgkin Lymphoma; Classical Hodgkin Lymphoma; HIV Infection; Locally Advanced Malignant Neoplasm; Metastatic Malignant Neoplasm; Recurrent Hepatocellular Carcinoma; Recurrent Hodgkin Lymphoma; Recurrent Kaposi Sarcoma; Recurrent Malignant Neoplasm; Recurrent Melanoma of the Skin; Recurrent Non-Hodgkin Lymphoma; Recurrent Non-Small Cell Lung Carcinoma; Refractory Hodgkin Lymphoma; Refractory Malignant Neoplasm; Solid Neoplasm; Stage IIIA Hepatocellular Carcinoma; Stage IIIA Non-Small Cell Lung Cancer; Stage IIIA Skin Melanoma; Stage IIIB Hepatocellular Carcinoma; Stage IIIB Skin Melanoma; Stage IIIC Hepatocellular Carcinoma; Stage IIIC Skin Melanoma; Stage IV Non-Small Cell Lung Cancer; Stage IV Skin Melanoma; Stage IVA Hepatocellular Carcinoma; Stage IVB Hepatocellular Carcinoma; Stage IVB Hepatocellular Carcinoma; Stage IVB Hepatocellular Carcinoma; Stage IVB Hepatocellular	Other: Laboratory Biomarker Analysis; Biological: Pembrolizumab	MD; WA	NCT02595866
A Prospective Randomized and Phase 2 Trial for Metastatic Melanoma Using Adoptive Cell Therapy With Tumor Infiltrating Lymphocytes Plus IL-2 Either Alone or Following the Administration of Pembrolizumab	Melanoma	Drug: Cyclophosphamide; Drug: Fludarabine; Drug: Aldeslaukin; Drug: Pembrolizumab; Biological: young TIL	MD	NCT02621021
Combining PD-1 Blockade, CD137 Agonism and Adoptive Cell Therapy for Metastatic Melanoma	Melanoma (Skin); Skin Cancer	Drug: Nivolumab; Procedure: Surgery to Remove Tumor for Growth of Til.; Drug: CD137; Drug: Cyclophosphamide; Drug: Fludarabine; Biological: TIL Infusion; Drug: Interleukin-2	FL	NCT02652455
A Pilot Study to Evaluate the Safety and Efficacy of Combination Checkpoint Blockade Plus External Beam Radiotherapy in Subjects With Stage IV Melanoma	Melanoma	Drug: Ipilimumab; Drug: Nivolumab; Radiation: Radiotherapy	CA; NY	NCT02659540
Phase I Study of Ipilimumab (Immunotherapy) and MGN1703 (TLR Agonist) in Patients With Advanced Solid Malignancies	Advanced Cancers; Melanoma	Drug: MGN1703; Drug: Ipilimumab	TX	NCT02668770
Phase 1 Study of GRN-1201 in HLA-A*02 Subjects With Resected Melanoma	Melanoma	Biological: GRN-1201	OH; OR; PA; UT	NCT02696356
Ipilimumab vs Ipilimumab Plus Nivolumab in Patients With Stage III-IV Melanoma Who Have Progressed or Relapsed on PD-1 Inhibitor Therapy	Melanoma	Drug: ipilimumab; Drug: nivolumab	NY	NCT02731729
GI Complications in Cancer Immunotherapy Patients	Malignant Melanoma		MA	NCT02784366
A Phase II Study of High Dose Bolus IL2 in Patients With Inoperable Stage III or Stage IV Melanoma Who Have Failed Prior Anti-PD1 Immunotherapy: Efficacy and Biomarker Study	Melanoma	Drug: High dose bolus interleukin-2 (HD IL2)	PA	NCT02796352
Adoptive T Cell Immunotherapy for Advanced Melanoma Using Engineered Lymphocytes	Melanoma	Biological: Escalating Doses	IL	NCT02870244
Trial of Intratumoral Injections of TTI-621 in Subjects With Relapsed and Refractory Solid Tumors and Mycosis Fungoides	Solid Tumors; Mycosis Fungoides; Melanoma; Merkel-cell Carcinoma; Squamous Cell Carcinoma; Breast Carcinoma; Human Papillomavirus-Related Malignant Neoplasm; Soft Tissue Sarcoma	Drug: TTI-621	CA; OR; PA; WA	NCT02890368
A Personalized Cancer Vaccine (NEO-PV-01) w/ Nivolumab for Patients With Melanoma, Lung Cancer or Bladder Cancer	Urinary Bladder Cancer; Bladder Tumors; Transitional Cell Carcinoma of the Bladder; Malignant Melanoma; Melanoma; Skin Cancer; Carcinoma, Non-Small-Cell Lung; Lung Cancer	Biological: NEO-PV-01; Biological: Nivolumab; Other: Adjuvant	CA; MA; TX	NCT02897765
Yttrium90, Ipilimumab, & Nivolumab for Uveal Melanoma With Liver Metastases	Uveal Melanoma; Hepatic Metastases	Device: SIR-Spheres Yttrium 90; Drug: ipilimumab; Drug: nivolumab	IL; PA	NCT02913417

# **MISCELLANEOUS**

Title	Cancer Type	Treatment	Location	NCT Number
Study of Cytokines in Children With Opsoclonus-Myoclonus Syndrome	Opsoclonus-myoclonus Syndrome		IL	NCT00806182
Natural History Study of SCID Disorders	SCID; Leaky SCID; Omenn Syndrome; Reticular Dysgenesis; ADA Deficiency; XSCID		AL; AZ; CA; CO; DC; DE; FL; GA; IL; LA; MA; MD; MI; MN; MO; NC; NJ; NY; OH; OR; PA; TX; UT; WA; WI	NCT01186913

#### MISCELLANEOUS (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Patients Treated for SCID (1968-2010)	SCID; ADA-SCID; XSCID; Leaky SCID; Omenn Syndrome; Reticular Dysgenesis		AL; CA; CO; DC; FL; GA; IL; LA; MA; MD; MI; MN; MO; NC; NJ; NY; OH; OR; PA; TX; UT; WA; WI	NCT01346150
Human Placental-Derived Stem Cell Transplantation	Mucopolysaccharidosis I; Mucopolysaccharidosis VI; Adrenoleukodystrophy; Niemann-Pick Disease; Metachromatic Leukodystrophy; Wolman Disease; Krabbe's Disease; Gaucher's Disease; Fucosidosis; Batten Disease; Severe Aplastic Anemia; Diamond-Blackfan Anemia; Amegakaryocytic Thrombocytopenia; Myelodysplastic Syndrome; Acute Myelogenous Leukemia; Acute Lymphocytic Leukemia	Drug: Human Placental Derived Stem Cell	CO; NY; UT	NCT01586455
Ipilimumab and Imatinib Mesylate in Advanced Cancer	Advanced Cancers	Drug: Ipilimumab; Drug: Imatinib Mesylate	TX	NCT01738139
Immunotherapy for Recurrent Ependymomas in Children Treatment for Recurrent Ependymomas Using HLA-A2 Restricted Tumor Antigen Peptides in Combination With Imiquimod	Ependymoma	Biological: HLA-A2 restricted synthetic tumor antigen; Drug: Imiquimod; Other: enzyme-linked immunosorbent assay; Other: flow cytometry; Other: immunohistochemistry staining method; Other: laboratory biomarker analysis	PA	NCT01795313
Safety Study of Intratumoral Injection of Clostridium Novyi-NT Spores to Treat Patients With Solid Tumors That Have Not Responded to Standard Therapies	Solid Tumor Malignancies	Biological: Clostridium novyi-NT spores	IL; MD; MI; MO; NY; OH; TX	NCT01924689
Tocilizumab and Hemophagocytic Lymphohistiocytosis (HLH)	Hemophagocytic Lymphohistiocytosis	Drug: tocilizumab	PA	NCT02007239
A Phase 1 Study of AM0010 in Patients With Advanced Solid Tumors	Melanoma; Prostate Cancer; Ovarian Cancer; Renal Cell Carcinoma; Colorectal Carcinoma; Pancreatic Carcinoma; Non-small Cell Lung Carcinoma; Solid Tumors; Breast Cancer	Drug: AM0010; Drug: Paclitaxel or Docetaxel and Carboplatin or Cisplatin; Drug: FOLFOX (Oxaliplatin/Leucovorin/5- Fluorouracill); Drug: gemcitabine/ nab-paclitaxel; Drug: Capecitabine; Drug: Pazopanib; Drug: Pembrolizumab; Drug: Paclitaxel; Drug: nivolumab; Drug: Gemcitabine/carboplatin	CA; CO; FL; MA; NY; OK; TN; TX	NCT02009449
Patients Treated for Chronic Granulomatous Disease (CGD) Since 1995	Granulomatous Disease, Chronic		AL; AZ; CA; CO; DC; DE; FL; GA; IL; LA; MA; MD; MI; MN; MO; NC; NJ; NY; OH; OR; PA; TX; UT; WA; WI	NCT02082353
T Cell Receptor Immunotherapy Targeting MAGE-A3 for Patients With Metastatic Cancer Who Are HLA-DP0401 Positive	Metastatic Cancer That Express the MAGE- A3-DP4 Antigen	Biological: Anti-MAGE-A3-DP4 TCR; Drug: Cyclophosphamide; Drug: Fludarabine; Drug: Aldesleukin	MD	NCT02111850
Immunotherapy in Subjects With HPV-6 Associated Aerodigestive Precancerous Lesions and Malignancies	Aerodigestive Precancerous Lesions and Malignancies	Biological: INO-3106, INO-9012	PA	NCT02241369
Study Of OX40 Agonist PF-04518600 Alone And In Combination With 4-1BB Agonist PF-05082566	Neoplasms	Drug: PF-04518600; Drug: PF-04518600; Drug: PF-04518600 plus PF-05082566; Drug: PF-04518600 plus PF-05082566	CA; TX; WA	NCT02315066
A Phase 1 Study of MEDI0562 in Adult Subjects With Selected Advanced Solid Tumors	Advanced Solid Tumors	Biological: MEDI0562	CA; MN; NC; NY; OR; PA; TX	NCT02318394
Study of the Kinetics, Dosimetry and Safety of [18F]F-AraG, a Positron Emission Tomography Imaging Tracer	Cancer	Drug: [18F]F-AraG	CA	NCT02323893
Adoptive Immunotherapy With Activated Marrow Infiltrating Lymphocytes and Cyclophosphamide Graft-Versus-Host Disease Prophylaxis in Patients With Relapse of Hematologic Malignancies After Allogeneic Hematopoietic Cell Transplantation	Hematologic Malignancies; Graft-Versus-Host Disease	Biological: Activated PTCy-MILs	MD	NCT02342613
Phase IIA Open Label Study to Evaluate Efficacy and Safety of BL-8040 Followed by (hATG), Cyclosporine and Methyprednisolone in Adult Subjects With Aplastic Anemia or Hypoplastic Myelodysplastic Syndrome	Aplastic Anemia; Hypoplastic Myelodysplastic Syndrome	Drug: BL-8040; Drug: horse anti-thymocyte globulin (hATG); Drug: Methylprednisolone; Drug: Cyclosporine	TX	NCT02462252
A Study of BBI608 Administered in Combination With Immune Checkpoint Inhibitors in Adult Patients With Advanced Cancers	Cancer	Drug: BBI608; Drug: Ipilimumab; Drug: Nivolumab; Drug: Pembrolizumab	GA; IL; MA; NY; SC	NCT02467361
Study of the CD40 Agonistic Monoclonal Antibody APX005M	Cancer; Carcinoma; Neoplasms; Neoplasm Metastasis	Drug: APX005M	CA; PA; TN	NCT02482168
GSK3174998 Alone or With Pembrolizumab in Subjects With Advanced Solid Tumors (ENGAGE-1)	Cancer	Drug: GSK3174998; Drug: Pembrolizumab	MA; NY; TN; TX	NCT02528357
A Study Of Avelumab In Combination With Other Cancer Immunotherapies In Advanced Malignancies (JAVELIN Medley)	Advanced Cancer	Drug: Avelumab; Drug: PF-05082566; Drug: PF-04518600; Drug: PF-04518600	CA; DC; FL; GA; MA; MI; NC; PA; TN; TX; WA	NCT02554812

# MISCELLANEOUS (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Combination of Interferon-gamma and Nivolumab for Advanced Solid Tumors	Advanced Solid Tumors	Drug: interferon-gamma and nivolumab	PA	NCT02614456
The PRONTO Study, a Global Phase 2b Study of NEOD001 in Previously Treated Subjects With Light Chain (AL) Amyloidosis	AL Amyloidosis	Drug: NEOD001; Drug: Placebo	CA; CO; FL; IL; IN; MA; MI; MN; NC; NY; OH; OR; PA; TN; TX; WA; WI	NCT02632786
Gene-Modified T Cells in Treating Patients With Locally Advanced or Stage IV Solid Tumors Expressing NY-ES0-1	Adult Solid Neoplasm	Drug: Cyclophosphamide; Other: Laboratory Biomarker Analysis; Biological: NY-ESO-1 Reactive TCR Retroviral Vector Transduced Autologous PBL; Biological: TGFbDNRII-transduced Autologous Tumor Infiltrating Lymphocytes	NY	NCT02650986
AGEN-1884, an Anti-CTLA-4 Antibody, in Advanced Solid Cancers	Advanced Solid Cancers	Drug: AGEN1884	FL; IL; NC; OH	NCT02694822
A Study of Ixekizumab (LY2439821) in TNF Inhibitor Experienced Participants With Radiographic Axial Spondyloarthritis	Spondyloarthritis	Drug: lxekizumab; Drug: Placebo	AZ; CA; CO; CT; FL; GA; ID; IN; KS; KY; MD; MO; NC; NY; OR; PA; SC; TX; VA; WA; WI	NCT02696798
Phase II Trial of Salvage Radiation Therapy to Induce Systemic Disease Regression After Progression on Systemic Immunotherapy	Metastatic Cancer	Radiation: Radiation Therapy	TX	NCT02710253
A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an Anti-PD-1 Monoclonal Antibody, in Patients With Advanced Solid Tumors	Advanced or Metastatic Solid Tumors	Biological: TSR-042	AZ; TX	NCT02715284
Safety and Immunogenicity of Personalized Genomic Vaccine to Treat Solid Tumors	Solid Tumors	Biological: Peptides; Drug: Poly-ICLC	NY	NCT02721043
Research Study Utilizing Expanded Multi-antigen Specific Lymphocytes for the Treatment of Solid Tumors	Solid Tumors	Biological: Tumor associated antigen lymphocytes (TAA-CTL)	DC	NCT02789228
A Study of the Effects of ALKS 4230 on Subjects With Solid Tumors	Advanced Solid Tumors	Drug: ALKS 4230	MI; OH	NCT02799095
Phase 1/2 Study of Mocetinostat and Durvalumab in Patients With Advanced Solid Tumors and NSCLC	Advanced Cancer	Drug: mocetinostat; Drug: durvalumab	NJ; NY; TX; WA	NCT02805660
A Phase 1 Study of TSR-022, an Anti-TIM-3 Monoclonal Antibody, in Patients With Advanced Solid Tumors	Advanced or Metastatic Solid Tumors	Drug: TSR-022; Drug: anti PD-1 antibody	AZ; CA; CO; FL; IL; TN	NCT02817633
Checkpoint Blockade Immunotherapy Combined With Stereotactic Body Radiation in Advanced Metastatic Disease	Metastatic Cancer	Drug: CBI; Radiation: CBI plus SBRT	CA	NCT02843165
18F-Clofarabine PET/CT in Imaging Cancer Patients Before and After Interventions	Malignant Neoplasm	Procedure: Computed Tomography; Radiation: Fluorine F 18 Clofarabine; Procedure: Positron Emission Tomography	CA	NCT02888301
Trial of Intratumoral Injections of TTI-621 in Subjects With Relapsed and Refractory Solid Tumors and Mycosis Fungoides	Solid Tumors; Mycosis Fungoides; Melanoma; Merkel-cell Carcinoma; Squamous Cell Carcinoma; Breast Carcinoma; Human Papillomavirus-Related Malignant Neoplasm; Soft Tissue Sarcoma	Drug: TTI-621	CA; OR; PA; WA	NCT02890368
Study to Evaluate the Safety and Pharmacokinetics of MEDI9090 in Subjects With Advanced Solid Tumors	Advanced Solid Tumors	Biological: MEDI9090; Biological: Durvalumab	NC; TX	NCT02900157
Dose Escalation and Expansion of JTX-2011 Alone or in Combination With Anti-PD-1 in Subjects With Advanced Solid Tumors	Cancer	Drug: JTX-2011; Drug: nivolumab	CO; TN; TX	NCT02904226
Glypican 3-specific Chimeric Antigen Receptor Expressed in T Cells for Patients With Pediatric Solid Tumors (GAP)	Solid Tumors	Genetic: GAP T cells; Drug: Cytoxan; Drug: Fludara	TX	NCT02932956

# NEUROENDOCRINE

Title	Cancer Type	Treatment	Location	NCT Number
Phase 2 STIR Trial: Haploidentical Transplant and Donor Natural Killer Cells for Solid Tumors	Ewing Sarcoma; Neuroblastoma; Rhabdo- myosarcoma; Osteosarcoma; CNS Tumors	Procedure: Allogeneic HCT; Drug: Donor NK Cell Infusion	WI	NCT02100891
Anti-GD2 3F8 Monoclonal Antibody and GM-CSF for High- Risk Neuroblastoma	Neuroblastoma	Biological: Anti-GD2 3F8 Monoclonal Antibody; Drug: GM-CSF (granulocyte- macrophage colony-stimulating factor); Drug: oral isotretinoin	NY	NCT02100930
A Phase I Trial of T Cells Expressing an Anti-GD2 Chimeric Antigen Receptor in Children and Young Adults With GD2+ Solid Tumors	Sarcoma; Osteosarcoma; Neuroblastoma; Melanoma	Biological: Anti-GD2-CAR engineered T cells; Drug: AP1903; Drug: Cyclophosphamide	MD	NCT02107963

# NEUROENDOCRINE (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
A Pilot Study of Immunotherapy Including Haploidentical NK Cell Infusion Following CD133+ Positively-Selected Autologous Hematopoietic Stem Cells in Children With High Risk Solid Tumors or Lymphomas	Neuroblastoma; Lymphoma; High-risk Tumor	Device: CD133+ selected autologous stem cell infusion; Biological: IL-2; Biological: hu14.18K322A; Drug: Busulfan; Drug: Melphalan; Biological: GM-CSF; Drug: Bendamustine; Drug: Etoposide; Drug: Cytarabine; Drug: Carboplatin; Device: Haploidentical natural killer cell infusion; Biological: G-CSF; Drug: Etoposide phosphate	TN	NCT02130869
Pembrolizumab in Treating Patients With Advanced Merkel Cell Cancer	Recurrent Merkel Cell Carcinoma; Stage IIIA Merkel Cell Carcinoma; Stage IIIB Merkel Cell Carcinoma; Stage IV Merkel Cell Carcinoma	Other: Laboratory Biomarker Analysis; Biological: Pembrolizumab	CA; CT; FL; GA; LA; MD; NY; OH; PA; WA	NCT02267603
Engineered Neuroblastoma Cellular Immunotherapy (ENCIT)-01	Neuroblastoma; Ganglioneuroblastoma	Biological: Patient Derived CD171 specific CAR T cells expressing EGFRt (2nd generation T cells); Biological: Patient Derived CD171 specific CAR T cells expressing EGFRt (3rd generation T cells)	WA	NCT02311621
Pediatric Precision Laboratory Advanced Neuroblastoma Therapy	Neuroblastoma	Drug: bortezomib; Drug: crizotinib; Drug: dasatinib; Drug: lapatinib; Drug: sorafenib; Drug: vorinostat; Drug: DFMO	AR; CA; CT; HI; MI; MN; MO; NC; PA; SC; TX	NCT02559778
Immunotherapy of Relapsed Refractory Neuroblastoma With Expanded NK Cells	Neuroblastoma	Drug: Ch14.18; Biological: NK Cells; Drug: Lenalidomide	CA; GA; IL; MA; MI; NY; OH; PA; TX; WA	NCT02573896
Localized Radiation Therapy or Recombinant Interferon Beta and Avelumab With or Without Cellular Adoptive Immunotherapy in Treating Patients With Metastatic Merkel Cell Carcinoma	Merkel Cell Polyomavirus Infection; Stage IV Merkel Cell Carcinoma	Drug: Avelumab; Other: Laboratory Biomarker Analysis; Biological: MCPyV TAg-specific Polyclonal Autologous CD8-positive T Cells; Radiation: Radiation Therapy; Biological: Recombinant Interferon Beta	WA	NCT02584829
Trial of Intratumoral Injections of TTI-621 in Subjects With Relapsed and Refractory Solid Tumors and Mycosis Fungoides	Solid Tumors; Mycosis Fungoides; Melanoma; Merkel-cell Carcinoma; Squamous Cell Carcinoma; Breast Carcinoma; Human Papillomavirus-Related Malignant Neoplasm; Soft Tissue Sarcoma	Drug: TTI-621	CA; OR; PA; WA	NCT02890368

# **OVARIAN**

Title	Cancer Type	Treatment	Location	NCT Number
CAR T Cell Receptor Immunotherapy Targeting Mesothelin for Patients With Metastatic Cancer	Cervical Cancer; Pancreatic Cancer; Ovarian Cancer; Mesothelioma; Lung Cancer	Drug: Fludarabine; Biological: Anti- mesothelin CAR; Drug: Cycolphosphamide; Drug: Aldesleukin	MD	NCT01583686
A Phase 1 Study of AM0010 in Patients With Advanced Solid Tumors	Melanoma; Prostate Cancer; Ovarian Cancer; Renal Cell Carcinoma; Colorectal Carcinoma; Pancreatic Carcinoma; Non-small Cell Lung Carcinoma; Solid Tumors; Breast Cancer	Drug: AM0010; Drug: Paclitaxel or Docetaxel and Carboplatin or Cisplatin; Drug: FOLFOX (Oxaliplatin/Leucovorin/5- Fluorouracil); Drug: gemcitabine/ nab-paclitaxel; Drug: Capecitabine; Drug: Pazopanib; Drug: Pembrolizumab; Drug: Paclitaxel; Drug: nivolumab; Drug: Gemcitabine/carboplatin	CA; CO; FL; MA; NY; OK; TN; TX	NCT02009449
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer; Head and Neck Squamous Cell Cancer; Ovarian Cancer; Colorectal Cancer; Gastric Cancer; Esophageal Cancer; Hepatocellular Cancer	Biological: INO-1400; Biological: INO-9012	MI; NC; PA	NCT02327468
Phase II/III Trial of Maintenance Vigil for High Risk Stage III/IV Ovarian Cancer	Ovarian Cancer; Ovarian Neoplasms	Biological: Vigil; Biological: Placebo	AL; CA; FL; GA; KY; MA; MI; MT; NC; NE; NH; NM; OK; PA; SC; TX; WA	NCT02346747
PARP-inhibition and CTLA-4 Blockade in BRCA-deficient Ovarian Cancer	Ovarian Cancer; Fallopian Tube Cancer; Peritoneal Neoplasms	Drug: Olaparib; Drug: Tremelimumab	NM	NCT02571725
GL-ONC1 Oncolytic Immunotherapy in Patients With Recurrent Ovarian Cancer	Ovarian Cancer; Peritoneal Carcinomatosis; Fallopian Tube Cancer	Biological: GL-ONC1	FL	NCT02759588
Study of DPX-Survivac Vaccine Therapy and Epacadostat in Patients With Recurrent Ovarian Cancer	Recurrent Epithelial Ovarian Cancer; Recurrent Fallopian Tube Cancer; Recurrent Peritoneal Cancer	Biological: DPX-Survivac; Drug: Cyclophosphamide; Drug: Epacadostat (INCB024360)	NY; OR; TX	NCT02785250
Intraperitoneal Infusion of Autologous Monocytes With Sylatron (Peginterferon Alfa-2b) and Actimmune (Interferon Gamma-1b) in Women With Recurrent or Refractory Ovarian Cancer, Fallopian Tube Cancer or Primary Peritoneal Cancer	Fallopian Tube Cancer; Ovarian Cancer; Primary Peritoneal Cancer	Biological: Autologous Monocytes + ACTIMMUNE + SYLATRON	MD	NCT02948426

# **PANCREATIC**

Title	Cancer Type	Treatment	Location	NCT Number
A Trial of Boost Vaccinations of Pancreatic Tumor Cell Vaccine	Pancreatic Cancer	Biological: PANC 10.05 pcDNA-1/GM-Neo and PANC 6.03 pcDNA-1 neo vaccine.	MD	NCT01088789
CAR T Cell Receptor Immunotherapy Targeting Mesothelin for Patients With Metastatic Cancer	Cervical Cancer; Pancreatic Cancer; Ovarian Cancer; Mesothelioma; Lung Cancer	Drug: Fludarabine; Biological: Anti- mesothelin CAR; Drug: Cycolphosphamide; Drug: Aldesleukin	MD	NCT01583686

# PANCREATIC (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
A Phase 2, Multicenter Study of FOLFIRINOX Followed by Ipilimumab With Allogenic GM-CSF Transfected Pancreatic Tumor Vaccine in the Treatment of Metastatic Pancreatic Cancer	Metastatic Pancreatic Adenocarcinoma	Drug: Ipilimumab; Biological: Vaccine; Drug: FOLFIRINOX	CA; MD; MO	NCT01896869
Combination Chemotherapy With or Without Oregovomab Followed by Stereotactic Body Radiation Therapy and Nelfinavir Mesylate in Treating Patients With Locally Advanced Pancreatic Cancer	Pancreatic Adenocarcinoma; Resectable Pancreatic Cancer; Stage IA Pancreatic Cancer; Stage IB Pancreatic Cancer; Stage IIA Pancreatic Cancer; Stage IIB Pancreatic Cancer; Stage III Pancreatic Cancer	Procedure: 4-Dimensional Computed Tomography, Drug: Fluorouracil; Drug: Gemcitabine Hydrochloride; Other: Laboratory Biomarker Analysis; Drug: Leucovorin Calcium; Drug: Nelfinavir Mesylate; Biological: Oregovomab; Radiation: Stereotactic Body Radiation Therapy, Procedure: Therapeutic Conventional Surgery	NE	NCT01959672
A Phase 1 Study of AM0010 in Patients With Advanced Solid Tumors	Melanoma; Prostate Cancer; Ovarian Cancer; Renal Cell Carcinoma; Colorectal Carcinoma; Pancreatic Carcinoma; Non-small Cell Lung Carcinoma; Solid Tumors; Breast Cancer	Drug: AM0010; Drug: Paclitaxel or Docetaxel and Carboplatin or Cisplatin; Drug: FOLFOX (Oxaliplatin/Leucovorin/5- Fluorouracil); Drug: apencitabine/ nab-paclitaxel; Drug: Capecitabine; Drug: Pazopanib; Drug: Pembrolizumab; Drug: Paclitaxel; Drug: nivolumab; Drug: Gemcitabine/carboplatin	CA; CO; FL; MA; NY; OK; TN; TX	NCT02009449
Safety and Immunological Effect of Pembrolizumab in Resectable or Borderline Resectable Pancreatic Cancer	Pancreatic Cancer	Drug: Pembrolizumab; Radiation: Neoadjuvant Chemoradiation	FL; TX; VA	NCT02305186
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer; Head and Neck Squamous Cell Cancer; Ovarian Cancer; Colorectal Cancer; Gastric Cancer; Esophageal Cancer; Hepatocellular Cancer	Biological: INO-1400; Biological: INO-9012	MI; NC; PA	NCT02327468
Neoadjuvant GMCI Plus mFOLFIRINOX and Chemoradiation for Non-Metastatic Pancreatic Adenocarcinoma	Pancreatic Adenocarcinoma	Biological: GMCl; Drug: mFOLFIRINOX; Drug: Gemcitabine; Radiation: Radiation; Procedure: Surgery	OH	NCT02446093
ALT-803 in Patients With Advanced Pancreatic Cancer Conjunction With Gemcitabine and Nab-Paclitaxel	Advanced Pancreatic Cancer	Biological: Gemcitabine; Biological: Nab- paclitaxel; Biological: ALT-803	HI	NCT02559674
Phase Ib/II Study of MEDI4736 Evaluated in Different Combinations in Metastatic Pancreatic Ductal Carcinoma	Metastatic Pancreatic Ductal Adenocarcinoma	Drug: MEDI4736 in combination with nab-paclitaxel and gemcitabine; Drug: MEDI4736 in combination with AZD5069	CA; NY; PA	NCT02583477
Study With CY, Pembrolizumab, GVAX, and SBRT in Patients With Locally Advanced Pancreatic Cancer	Pancreatic Cancer	Drug: Cyclophosphamide; Drug: GVAX; Drug: Pembrolizumab; Radiation: SBRT	MD	NCT02648282
A Study of Galunisertib (LY2157299) and Durvalumab (MEDI4736) in Participants With Metastatic Pancreatic Cancer	Metastatic Pancreatic Cancer	Drug: Galunisertib; Drug: Durvalumab	AZ; NY; TN	NCT02734160

# **PENILE**

Title	Cancer Type	Treatment	Location	NCT Number
E7 TCR T Cells With or Without PD-1 Blockade for Human Papillomavirus-Associated Cancers	Cervical Cancer; Vaginal Cancer; Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Biological: E7 TCR cells; Drug: pembrolizumab; Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide	MD	NCT02858310

# PERITONEAL

Title	Cancer Type	Treatment	Location	NCT Number
PARP-inhibition and CTLA-4 Blockade in BRCA-deficient Ovarian Cancer	Ovarian Cancer; Fallopian Tube Cancer; Peritoneal Neoplasms	Drug: Olaparib; Drug: Tremelimumab	NM	NCT02571725
GL-ONC1 Oncolytic Immunotherapy in Patients With Recurrent Ovarian Cancer	Ovarian Cancer; Peritoneal Carcinomatosis; Fallopian Tube Cancer	Biological: GL-ONC1	FL	NCT02759588
Study of DPX-Survivac Vaccine Therapy and Epacadostat in Patients With Recurrent Ovarian Cancer	Recurrent Epithelial Ovarian Cancer; Recurrent Fallopian Tube Cancer; Recurrent Peritoneal Cancer	Biological: DPX-Survivac; Drug: Cyclophosphamide; Drug: Epacadostat (INCB024360)	NY; OR; TX	NCT02785250
Intraperitoneal Infusion of Autologous Monocytes With Sylatron (Peginterferon Alfa-2b) and Actimmune (Interferon Gamma-1b) in Women With Recurrent or Refractory Ovarian Cancer, Fallopian Tube Cancer or Primary Peritoneal Cancer	Fallopian Tube Cancer; Ovarian Cancer; Primary Peritoneal Cancer	Biological: Autologous Monocytes + ACTIMMUNE + SYLATRON	MD	NCT02948426

# PROSTATE

Title	Cancer Type	Treatment	Location	NCT Number
Adoptive Transfer of Autologous T Cells Targeted to Prostate Specific Membrane Antigen (PSMA) for the Treatment of Castrate Metastatic Prostate Cancer (CMPC)	Prostate Cancer	Biological: engineered autologous T cells; Drug: cyclophosphamide	NY	NCT01140373

# PROSTATE (CONTINUED)

PROSTATE (CONTINUED)		T .		
Title	Cancer Type	Treatment	Location	NCT Number
Efficacy Trial of the Implantation of Mouse Renal Adenocarcinoma Macrobeads in Subjects With Castration- Resistant Prostate Cancer Resistant to Taxanes (Docetaxel, Cabazitaxel) and Evidence of Disease Progression on Androgen-axis Inhibition and/or Immunotherapy in the Form of Sipuleucel-T	Prostate Cancer	Biological: Cancer Macrobead placement in abdominal cavity	NY	NCT01174368
Phase 3 Study of ProstAtak Immunotherapy With Standard Radiation Therapy for Localized Prostate Cancer	Prostate Cancer	Biological: ProstAtak(AdV-tk) + valacyclovir; Biological: Placebo + valacyclovir	AZ; CO; MA; MD; NM; NY; PA; TX	NCT01436968
C11-Sodium Acetate PET/CT Imaging for Metastatic Disease in Intermediate-to-high Risk Prostate Adenocarcinoma	Prostate Cancer; Prostate Adenocarcinoma	Drug: C11-Sodium Acetate	AZ	NCT01530269
A Randomized Phase 2 Trial of Combining Sipuleucel-T With Immediate vs. Delayed CTLA-4 Blockade for Prostate Cancer	Prostate Cancer	Drug: SipT Treatment; Drug: Ipilimumab	CA; TX	NCT01804465
Sipuleucel-T and Stereotactic Ablative Body Radiation (SABR) for Metastatic Castrate-resistant Prostate Cancer i(mCRPC)	Metastatic Castrate-resistant Prostate Cancer; mCRPC	Drug: Sipuleucel-T; Radiation: Stereotactic Ablative Body Radiation	TX	NCT01818986
Enzalutamide With or Without Vaccine Therapy for Advanced Prostate Cancer	Prostate Cancer	Biological: PROSTVAC-F/TRICOM; Biological: PROSTVAC-V/TRICOM; Drug: Enzalutamide (Xtandi)	MD	NCT01867333
Enzalutamide in Combination With PSA-TRICOM in Patients With Non-Metastatic Castration Sensitive Prostate Cancer	Prostate Cancer	Biological: PROSTVAC-F/TRICOM; Biological: PROSTVAC-V/TRICOM; Drug: Enzalutamide (Xtandi)	MD	NCT01875250
CYT107 After Vaccine Treatment (Provenge) in Patients With Metastatic Hormone-Resistant Prostate Cancer	Hormone-Resistant Prostate Cancer; Metastatic Prostate Carcinoma; Recurrent Prostate Carcinoma; Stage IV Prostate Cancer	Biological: Glycosylated Recombinant Human Interleukin-7; Other: Laboratory Biomarker Analysis	CA; GA; IL; MA; NC; NH; NY; OH; PA; WA	NCT01881867
A Phase 1 Study of AM0010 in Patients With Advanced Solid Tumors	Melanoma; Prostate Cancer; Ovarian Cancer; Renal Cell Carcinoma; Colorectal Carcinoma; Pancreatic Carcinoma; Non-small Cell Lung Carcinoma; Solid Tumors; Breast Cancer	Drug: AM0010; Drug: Paclitaxel or Docetaxel and Carboplatin or Cisplatin; Drug: FOLFOX (Oxaliplatin/Leucovorin/5- Fluorouracil); Drug: gemcitabine/ nab-paclitaxel; Drug: Capecitabine; Drug: Pazopanib; Drug: Pembrolizumab; Drug: Paclitaxel; Drug: nivolumab; Drug: Gemcitabine/carboplatin	CA; CO; FL; MA; NY; OK; TN; TX	NCT02009449
Dendreon Lymph Node Biopsy in Metastatic Castrate- Resistant Prostate Cancer	Prostate Cancer	Drug: Sipuleucel-T; Procedure: Lymph Node Biopsy	NC	NCT02036918
Phase III Study of DCVAC Added to Standard Chemotherapy for Men With Metastatic Castration Resistant Prostate Cancer	Metastatic Castrate Resistant Prostate Cancer	Biological: Dendritic Cells DCVAC; Biological: Placebo; Drug: Docetaxel; Drug: Taxotere	AL; AZ; CA; CO; CT; DC; FL; GA; KS; LA; MA; MD; MI; MN; NC; NE; NJ; NV; NY; OH; OR; PA; SC; TN; TX; UT; VA; WA; WV	NCT02111577
Pilot Study of DRibble Vaccine for Prostate Cancer Patients	Adenocarcinoma of the Prostate	Drug: Cyclophosphamide; Biological: DRibble Vaccine; Biological: HPV Vaccinations; Drug: Imiquimod	OR	NCT02234921
Ph 2 Study of Sipuleucel-T W/ or W/O Radium-223 in Men With Asymptomatic or Minimally Symptomatic Bone- MCRPC	Prostate Cancer	Drug: Radium-223; Biological: Sipuleucel-T	DC; MD	NCT02463799
A Phase 1 Study To Evaluate Escalating Doses Of A Vaccine-Based Immunotherapy Regimen For Prostate Cancer (PrCa VBIR)	Prostatic Neoplasms	Biological: PF-06755992; Biological: PF-06755990; Device: TDS-IM Electroporation Device; Biological: Tremelimumab; Drug: Sunitinib	CT; MD; NC; NE; NV; NY; PA; WA	NCT02616185
Safety & Immunogenicity of JNJ-64041809, a Live Attenuated Double-deleted Listeria Immunotherapy, in Participants With Metastatic Castration-resistant Prostate Cancer	Prostatic Neoplasms, Castration-Resistant	Biological: JNJ-64041809 (Cohort 1A and 1B); Biological: JNJ-64041809 (Cohort 2A and 2B)	CA; MD; MO; TN; TX; WI	NCT02625857
Prostvac in Patients With Biochemically Recurrent Prostate Cancer	Prostate Cancer	Biological: PROSTVAC -V; Biological: PROSTVAC-F; Other: Surveillance	MD	NCT02649439
Docetaxel and PROSTVAC for Metastatic Castration- Sensitive Prostate Cancer	Prostate Cancer; Prostate Neoplasms; Neoplasms, Prostatic	Biological: PROSTVAC-V; Biological: PROSTVAC-F; Drug: Docetaxel	MD	NCT02649855
PROMOTE: Identifying Predictive Markers of Response for Prostate Cancer	Prostate Cancer	Other: Systemic therapy	CA	NCT02735252
Randomized Controlled Trial of ProstAtak Immunotherapy During Active Surveillance for Prostate Cancer (ULYSSES)	Prostate Cancer	Biological: aglatimagene besadenovec; Biological: placebo; Drug: valacyclovir	TX	NCT02768363
Provenge Followed by Docetaxel in Castration-Resistant Prostate Cancer	Prostate Cancer	Biological: Sipuleucel-T; Drug: Docetaxel	TX	NCT02793219
Docetaxel Followed by Provenge in Metastatic Prostate Cancer	Prostate Cancer	Drug: Docetaxel; Biological: Sipuleucel-T	TX	NCT02793765
A Study of the Clinical Activity and Safety of JNJ-64041809, a Live Attenuated Listeria Monocytogenes Immunotherapy, in Combination With Apalutamide Versus Apalutamide in Subjects With Metastatic Castration-resistant Prostate Cancer	Prostatic Neoplasms, Castration-Resistant	Drug: JNJ-809; Drug: Apalutamide	MD	NCT02906605
PROSTVAC in Combination With Nivolumab and/or Ipilimumab in Men With Prostate Cancer	Prostate Cancer	Biological: PROSTVAC-V/F; Drug: Nivolumab; Drug: Ipilimumab	MD	NCT02933255

# **SARCOMA**

Title	Cancer Type	Treatment	Location	NCT Number
Her2 Chimeric Antigen Receptor Expressing T Cells in Advanced Sarcoma	Sarcoma	Genetic: Autologous HER2-specific T cells; Drug: Fludarabine; Drug: Cyclophosphamide	TX	NCT00902044
A Pilot Study of Genetically Engineered NY-ESO-1 Specific NY-ESO-1°259 in HLA-A2+ Patients With Synovial Sarcoma	Synovial Sarcoma	Biological: NY-ESO-1(c259)T Cells	CA; FL; MD; NY; PA	NCT01343043
T Cell Receptor Immunotherapy Targeting NY-ES0-1 for Patients With NY-ES0-1 Expressing Cancer	Synovial Sarcoma; Breast Cancer; Non-Small Cell Lung Cancer; Hepatocellular Cancer	Biological: Anti-NY ESO-1 mTCR PBL; Drug: Cyclophosphamide; Drug: Fludarabine; Drug: Aldesleukin	MD	NCT01967823
A Phase I Trial of T Cells Expressing an Anti-GD2 Chimeric Antigen Receptor in Children and Young Adults With GD2+ Solid Tumors	Sarcoma; Osteosarcoma; Neuroblastoma; Melanoma	Biological: Anti-GD2-CAR engineered T cells; Drug: AP1903; Drug: Cyclophosphamide	MD	NCT02107963
In Situ, Autologous Therapeutic Vaccination Against Solid Cancers With Intratumoral Hiltonol	Melanoma; Head and Neck Cancer; Sarcoma; Non-Melanoma Skin Cancers	Biological: Hiltonol	GA; MD; NY; PA	NCT02423863
Randomized Phase IIb Trial of Vigil Versus Gemcitabine + Docetaxel for Ewing's Sarcoma	Ewing's Sarcoma	Biological: Vigil; Drug: gemcitabine and docetaxel	CA; FL; NH; NY; OH; TX	NCT02511132
Trial of CMB305 and Atezolizumab in Patients With Sarcoma	Sarcoma; Myxoid/Round Cell Liposarcoma; Synovial Sarcoma; Metastatic Sarcoma; Recurrent Adult Soft Tissue Sarcoma; Locally Advanced Sarcoma; Liposarcoma	Biological: CMB305; Biological: atezolizumab	CA; CO; DC; FL; GA; IA; IL; MA; MN; MO; NC; NY; PA; TN; VT; WA	NCT02609984
Trial of Intratumoral Injections of TTI-621 in Subjects With Relapsed and Refractory Solid Tumors and Mycosis Fungoides	Solid Tumors; Mycosis Fungoides; Melanoma; Merkel-cell Carcinoma; Squamous Cell Carcinoma; Breast Carcinoma; Human Papillomavirus-Related Malignant Neoplasm; Soft Tissue Sarcoma	Drug: TTI-621	CA; OR; PA; WA	NCT02890368

#### STOMACH

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Title	Cancer Type	Treatment	Location	NCT Number
Trial of Active Immunotherapy With OBI-833 (Globo H-CRM197)in Gastric, Lung, Colorectal or Breast Cancer Subjects	Metastatic Gastric Cancer; Metastatic Breast Cancer; Metastatic Colorectal Cancer; Metastatic Lung Cancer	Drug: OBI-833/OBI-821	OH; TX	NCT02310464
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer; Head and Neck Squamous Cell Cancer; Ovarian Cancer; Colorectal Cancer; Gastric Cancer; Esophageal Cancer; Hepatocellular Cancer	Biological: INO-1400; Biological: INO-9012	MI; NC; PA	NCT02327468
A Phase 1b/2 Study of MEDI4736 With Tremelimumab, MEDI4736 or Tremelimumab Monotherapy in Gastric or GEJ Adenocarcinoma	Gastric or Gastroesophageal Junction Adenocarcinoma	Biological: MEDI4736 + tremelimumab; Biological: MEDI4736; Biological: Tremelimumab; Biological: MEDI4736 + tremelimumab	CA; CT; FL; IL; MD; NY; OH; OR; PA; SC; TN; TX	NCT02340975
Combination Margetuximab and Pembrolizumab for Advanced, Metastatic HER2(+) Gastric or Gastroesophageal Junction Cancer	Gastric Cancer; Stomach Cancer; Esophageal Cancer	Drug: margetuximab in combination with pembrolizumab	CT; DC; IL; MA; MD; MI; MO; NC; PA; TN; WA	NCT02689284
T Cell Immunotherapy Plus Anti-PD1 Antibody in Advanced Solid Malignancies	Gastrointestinal Cancer Metastatic	Drug: Standard Chemotherapy, Drug: Cyclophosphamide; Biological: Adoptive T Cell Infusion; Drug: IL-2; Drug: Pembrolizumab; Behavioral: Phone Calls	TX	NCT02757391

# **UTERINE**

Title	Cancer Type	Treatment	Location	NCT Number
MK-3475 Immunotherapy in Endometrial Carcinoma	Endometrial Carcinoma; Neoplasms, Endometrial	Drug: MK-3475; Procedure: Surgical resection (standard of care); Drug: Paclitaxel (standard of care); Drug: Carboplatin (standard of care); Radiation: Radiation (standard of care); Procedure: Endometrial biopsy; Procedure: Peripheral blood draw	MO	NCT02630823

# **VAGINAL**

Title	Cancer Type	Treatment	Location	NCT Number
E7 TCR T Cells With or Without PD-1 Blockade for Human Papillomavirus-Associated Cancers	Cervical Cancer; Vaginal Cancer; Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Biological: E7 TCR cells; Drug: pembrolizumab; Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide	MD	NCT02858310

# **ŠUPPORT & FINANCIAL RESOURCES**

#### **CANCER EDUCATION**

CANCELLEDOCATION	
American Cancer Society	www.cancer.org
American Society of Clinical Oncology	www.cancer.net
CANCER101	www.cancer101.org
Cancer <i>Care</i>	www.cancercare.org
CancerGuide	www.cancerguide.org
CancerQuest	www.cancerquest.org
Centers for Disease Control and Prevention (CDC)	www.cdc.gov
The Gathering Place	www.touchedbycancer.org
Get Palliative Care	www.getpalliativecare.org
Global Resource for Advancing Cancer Education (GRACE)	www.cancergrace.org
The Hope Light Foundation	www.hopelightproject.com
LIVESTRONG Foundation	www.livestrong.org
National Cancer Institute	www.cancer.gov
National Comprehensive Cancer Network (NCCN)	www.nccn.org
National LGBT Cancer Network	http://cancer-network.org
OncoLink	www.oncolink.org
Patient Power	
PearlPoint Cancer Support	www.pearlpoint.org
Pine Street Foundation	
R.A. Bloch Cancer Foundation	
Scott Hamilton Cares Foundation	
Triage Cancer	0 0
U.S. National Library of Medicine	www.nlm.nih.gov
CAREGIVERS & SUPPORT	

Cancer Action	•
Cancer and Careers	· ·
Cancer Care	
Cancer Connection	ũ .
Cancer Hope Network	
Cancer Information and Counseling Line	800-525-3777
Cancer Support Community	www.cancersupportcommunity.org
Cancer Support Helpline	
Cancer Survivors Network	http://csn.cancer.org
Cancer Wellness Center	www.cancerwellness.org
Caregiver Action Network	www.caregiveraction.org
CaringBridge	www.caringbridge.org
Center to Advance Palliative Care	www.capc.org
Cleaning For A Reason	www.cleaningforareason.org
Cooking with Cancer	www.cookingwithcancer.org
Cuddle My Kids	www.cuddlemykids.org
Family Caregiver Alliance	www.caregiver.org
Fighting Chance	www.fightingchance.org
Friend for Life Cancer Support Network	www.friend4life.org
The Gathering Place	www.touchedbycancer.org
Guide Posts of Strength, Inc.	www.cancergps.org
The Hope Light Foundation	www.hopelightproject.com
I Can Cope	www.cancer.org/icancope
Imerman Angels	www.imermanangels.org
The LGBT Cancer Project – Out With Cancer	www.lgbtcancer.org
LIVESTRONG Foundation	www.livestrong.org
LivingWell Cancer Resource Center	www.livingwellcrc.org
Lotsa Helping Hands	www.lotsahelpinghands.com
MyLifeLine.org Cancer Foundation	www.mylifeline.org
Patient Empowerment Network	www.powerfulpatients.org
Patient Power	www.patientpower.info
PearlPoint Cancer Support	
SHARE Caregiver Circle	
Strike Out Cancer	
Stronghold Ministry	www.mystronghold.org
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# **SUPPORT & FINANCIAL**

Support Groups	
Triage Cancer	
Turning Pointwww.turningpointkc.org	· · · · · · · · · · · · · · · · · · ·
Vital Options International	LivingWell Cancer Resource Center
Well Spouse Associationwww.wellspouse.org	Mautner Projectwww.whitman-walker.org/mautnerproject
weSPARK Cancer Support Centerwww.wespark.org	
Wonders & Worrieswww.wondersandworries.org	
	Patient Advocate Foundationwww.patientadvocate.org
CLINICAL TRIALS	Research Advocacy Networkwww.researchadvocacy.org
My Clinical Trial Locator	Vital Options Internationalwww.vitaloptions.org
National Cancer Institutewww.cancer.gov/clinicaltrials	
National Institutes of Healthwww.clinicaltrials.gov	
TrialCheckwww.trialcheck.org	
FINANCIAL ASSISTANCE	Cancer Care Co-Payment Assistance Foundationwww.cancercarecopay.org, 866-552-6729
BenefitsCheckUpwww.benefitscheckup.org	Cancer Financial Assistance Coalitionwww.cancerfac.org The CHAIN Fund Incwww.thechainfund.com, 203-691-5955
Bringing Hope Homewww.bringinghopehome.org	
Cancer Carewww.cancercare.org/financia	
Cancer Financial Assistance Coalitionwww.cancerfac.org	HealthWell Foundation
The CHAIN Fundwww.thechainfund.com	NeedyMedswww.needymeds.org, 800-503-6897
HealthWell Foundationwww.healthwellfoundation.org	Partnership for Prescription Assistance
Hope Lodgewww.cancer.org/treatment/supportprogramsservices/hopelodge	Patient Access Network Foundationwww.panfoundation.org, 866-316-PANF
Medicare.govwww.medicare.gov	Patient Advocate Foundation Co-Pay Reliefwww.copays.org, 866-512-3861
NeedyMedswww.needymeds.com	Patient Services, Incwww.patientservicesinc.org, 800-366-7741
Partnership for Prescription Assistance	11XM33131WWW.1Xd33131.UIY
Patient Access Network Foundationwww.panfoundation.org	11X1 IODE WWW.1X1IODE.CUIII, 077-207-0317
Patient Advocate Foundationwww.patientadvocate.org	nxUuti eaciiwww.ixUuti eacii.cuiii, 000-730-1234
Patient Services, Incwww.patientservicesinc.org RxAssistwww.rxassist.org	1046(116) 11X MCC699
RxHope www.rxhope.com	
Social Security Administration	
Social Security Disability Resource Center www.ssdrc.com	Tibb Tio Tation Chooletanes Tourisation
State Health Insurance Assistance Programs	
	Bayer Healthcare Pharmaceuticals
IMMUNOTHERAPY	Roehringer Ingelheim Cares Foundation
The Answer to Cancerwww.theanswertocancer.org	Patient Assistance Programhttp://us.boehringer-ingelheim.com, 800-556-8317
Cancer Research Institutewww.cancerresearch.org	
Immuno-Oncology	
Society for Immunotherapy of Cancerwww.sitcancer.org	Bristol-Myers Squibb Patient Assistance Foundationwww.bmspaf.org, 800-736-0003 Celgene Patient Support800-931-8691
LEGAL ISSUES	Darzalex Janssen CarePath Savings Programwww.carepathsavingsprogram.com, 844-553-2792
Administration on Aging (search for "legal assistance") www.aoa.gov, 202-401-4634	
American Bar Associationwww.americanbar.org, 800-285-2221	darzalex-cost-assistance, 844-553-2792
Cancer and Careerswww.cancerandcareers.org, 636-929-8032	Eisai Reimbursement Resourceswww.eisaireimbursement.com
Disability Rights Legal Centerwww.disabilityrightslegalcenter.org, 866-999-3752	Empliciti Patient Supportwww.empliciti.com/access, 844-367-5424
LawHelp.orgwww.lawhelp.org	
Legal Services Corporationwww.lsc.gov, 202-295-1500	
National Coalition for Cancer Survivorshipwww.canceradvocacy.org, 877-NCCS-YES	Ciland Dationt Assess
National Health Law Program (links to assistance programs)www.healthlaw.org, 202-289-7661	CCV Assess 000 02F E240
Patient Advocate Foundation	1441/010 0 4
Social Security Disability Resource Centerwww.ssdrc.com	Janssen Prescription Assistance
MENTAL HEALTH SERVICES	Johnson & Johnson Patient Assistance Foundation, Incwww.jjpaf.org, 800-652-6227
American Psychosocial Oncology Society Helpline	Vertical Detical Assistance
	Leukine Direct Reimbursement Support Linewww.leukine.com/patient-reimbursement,
NUTRITION	888-479-5385
American Cancer Societywww.cancer.org	Lyrica CoPay Savings Card www.lyrica.com/Lyrica_Co-pay_Download800-578-7076
Cancer Carewww.cancercare.org	14 1 1 1 1 200 707 5400
LIVESTRONG Foundationwww.livestrong.org	N C D C C A C C N C C C C C C C C C C C C C C
OncoLinkwww.oncolink.org	November Openium Universal Co Day Dragger Consultation and anti-
PearlPoint Cancer Supportwww.pearlpoint.org	DC 0 D 0
Physicians Committee for Responsible Medicinewww.pcrm.org/health/cancer-resources	Pfizer RxPathways
PAIN MANAGEMENT	R-PHARM US Access + Supporthttp://enrollsource.rpharm-us.com, 855-991-7277
American Chronic Pain Associationwww.theacpa.org	
Cancer Pain Research Consortiumwww.cancerpainresearchconsortium.org	
LIVESTRONG Foundationwww.livestrong.org	Sylatron Patient Assistancewww.merckhelps.com/SYLATRON, 855-257-3932
The Resource Center of the Alliance of State Pain Initiativeswww.trc.wisc.edu	Takeda Patient Assistancewww.takeda.us/responsibility/patient_assistance_program.aspx,
U.S. Pain Foundation	800-830-9159
DATIENT ADVOCACY	Teva Cares Foundation Patient Assistance Programswww.tevacares.org, 877-237-4881
PATIENT ADVOCACY  American Capacy Society Capacy Action Naturals  American Capacy Society Capacy Action Naturals	Teva Oncology Core Reimbursement Assistance & Support www.tevacore.com, 888-587-3263 Together with TESARO
American Cancer Society Cancer Action Networkwww.acscan.org Cancer Legal Resource Centerwww.disabilityrightslegalcenter.org/cancer-legal-resource-cente	
Cancer Legal Resource Centerwww.disabilityrightslegalcenter.org/cancer-legal-resource-cente  Dream Foundationwww.dreamfoundation.org	044 720 2001
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