Case Studies in Immunotherapy for the Treatment of Breast Cancer

December 1, 2021

11:30 a.m. – 12:30 p.m. ET

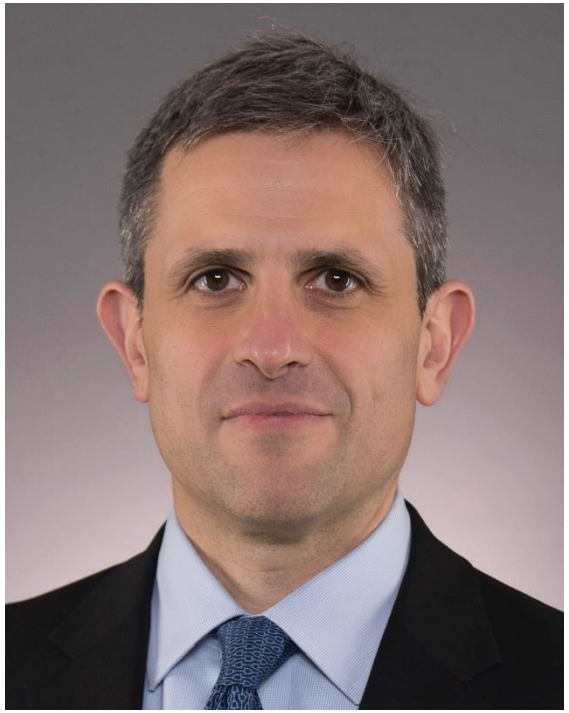
Society for Immunotherapy of Cancer

Cancer Immunotherapy GUIDELINES

The Practical Management Pearls and Case Studies Webinars are part of the Cancer Immunotherapy Clinical Practice Guidelines Advanced Webinar Series supported, in part, by grants from Amgen and Merck & Co., Inc. (as of 9/15/2021)

Webinar faculty

Jennifer Litton, MD – *The University of Texas MD Anderson Cancer Center*



Kevin Kalinsky, MD, MS– *Winship Cancer Insitute, Emory University*

Heather McArthur, MD, MPH – *UT Southwestern*

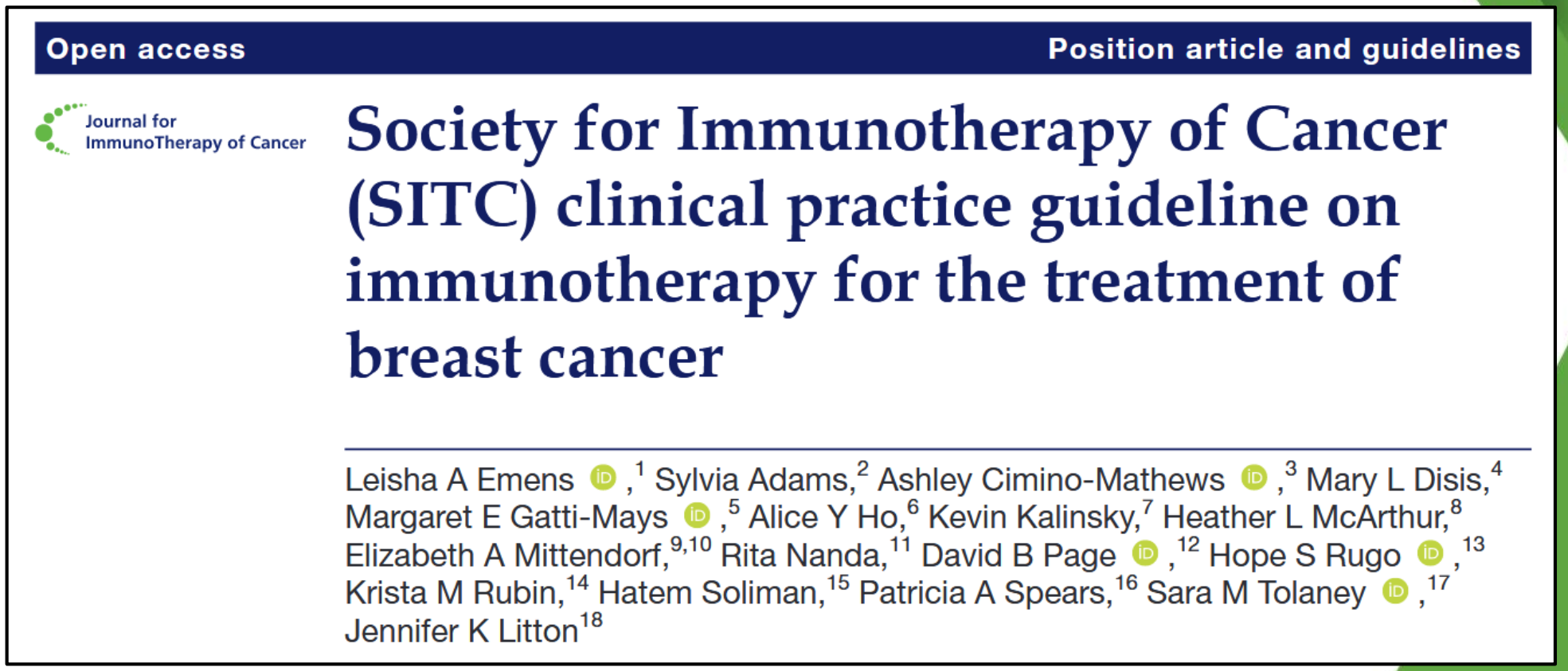
Learning objectives

- Plan immunotherapy treatment regimens for challenging patient populations
- Select appropriate treatment strategies for patients with early and metastatic triple negative breast cancer
- Identify management strategies for uncommon and/or atypically responsive toxicities

Webinar outline

- Development of the guideline
- Toxicity timeframes
  - How IO differs from chemo
- Case 1: Neoadjuvant therapy- Dr. Kevin Kalinsky
- Case 2: First-line metastatic – Dr. Heather MacArthur
- Key takeaways

Development of the Guideline



Open access Position article and guidelines

Journal for ImmunoTherapy of Cancer

Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of breast cancer

Leisha A Emens ,[1] Sylvia Adams,[2] Ashley Cimino-Mathews ,[3] Mary L Disis,[4] Margaret E Gatti-Mays ,[5] Alice Y Ho,[6] Kevin Kalinsky,[7] Heather L McArthur,[8] Elizabeth A Mittendorf,[9,10] Rita Nanda,[11] David B Page ,[12] Hope S Rugo ,[13] Krista M Rubin,[14] Hatem Soliman,[15] Patricia A Spears,[16] Sara M Tolaney ,[17] Jennifer K Litton[18]

Development of the Guideline

- Developed according to the Institute of Medicine's Standards for Developing Trustworthy Clinical Practice Guidelines
- Panel consisted of 17 experts in the field
- Recommendations are based upon published literature evidence, or clinical evidence where appropriate
- Consensus was defined at 75% approval among voting members

Webinar outline

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- Toxicity timeframes
  - How IO differs from chemo
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Toxicities Associated With Immune Checkpoint Inhibitors

	Chemotherapy	Immunotherapy
Incidence (moderate/severe AEs)	Almost all patients	Majority without
AE profile	Well described	Variable
Affected systems/organs	Few organs affected	Any organ
Time course	Well established	Variable (even after end of Tx)
	Predictable	Relatively unpredictable

Slide credit: clinicaloptions.com

Organs/Systems Affected by Immune-Related Side Effects

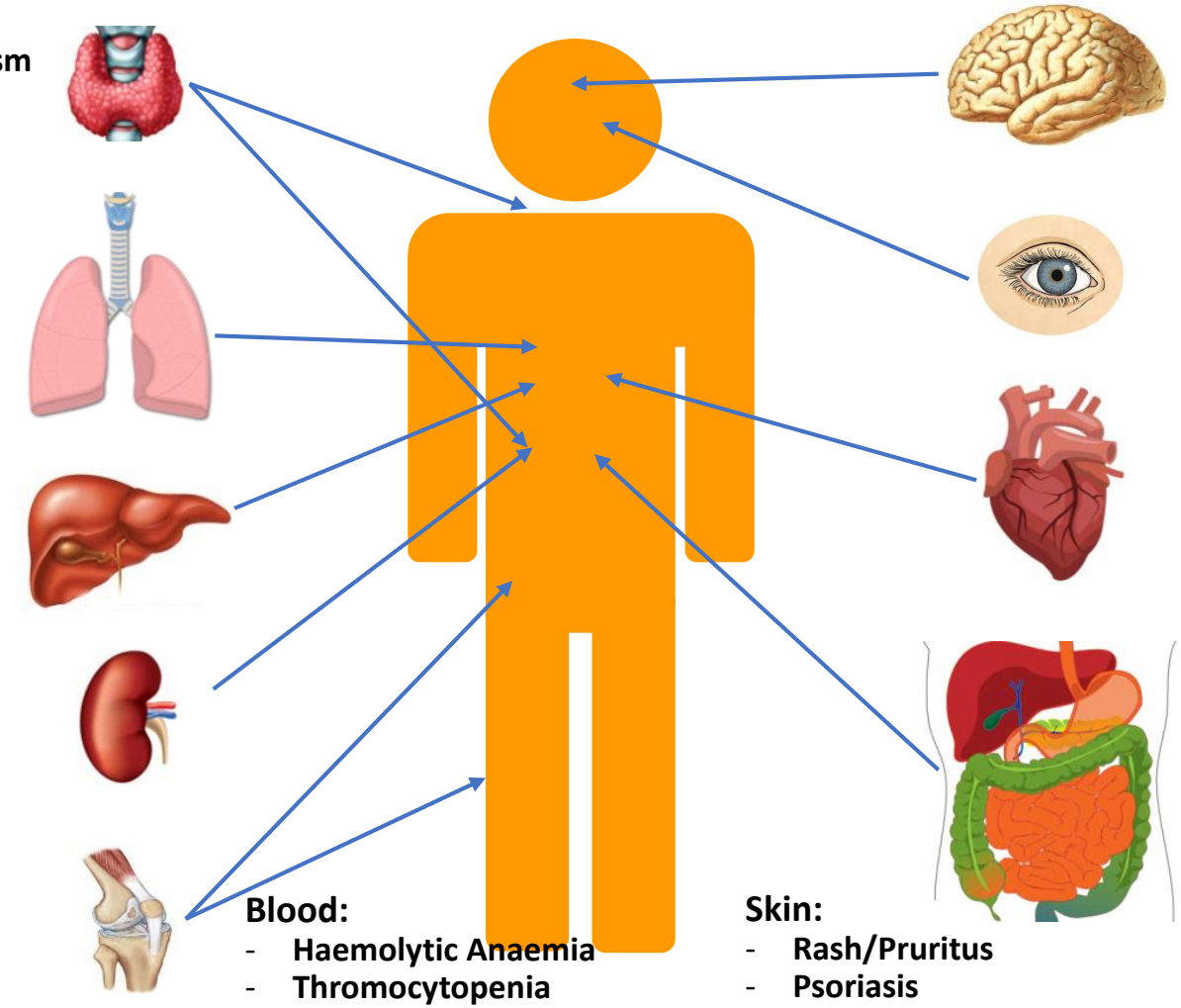
Endocrine:
- Hyper/Hypothyroidism
- Hypophysitis
- Adrenal insufficiency
- Diabetes

Respiratory:
- Pneumonitis
- Pleuritis
- Sarcoid

Liver:
- Hepatitis

Renal:
- Nephritis

Musculoskeletal:
- Arthritis
- Dermatomyositis



Blood:
- Haemolytic Anaemia
- Thromocytopenia
- Neutropenia
- Haemophilia

Skin:
- Rash/Pruritus
- Psoriasis
- Vitiligo
- Stevens Johnston

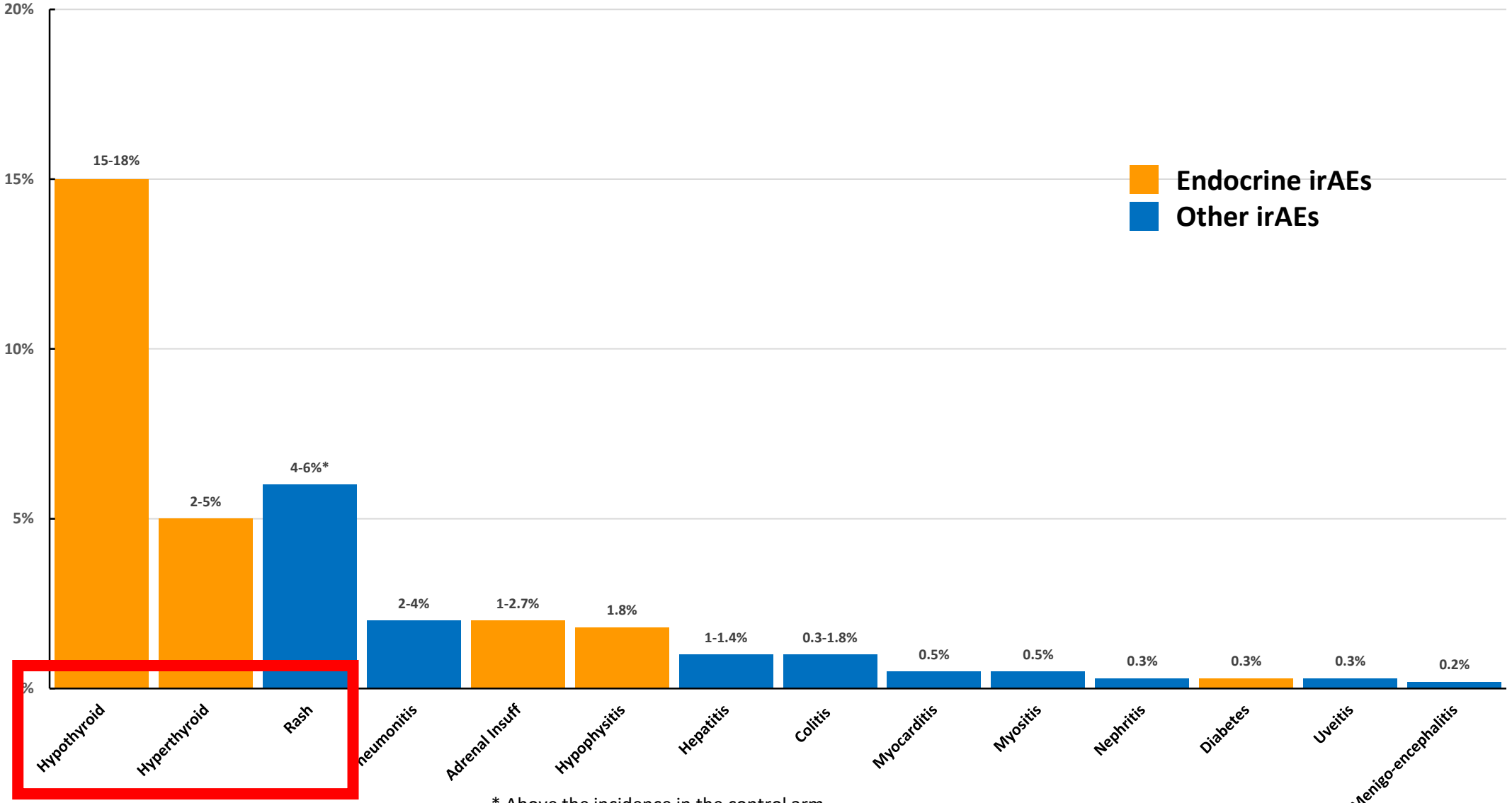
Neurologic:
- Meningitis/Encephalitis
- Guillain Barre
- Myelopathy/neuropathy
- Myasthenia

Eye:
- Uveitis/Scleritis
- Conjunctivitis/Blepharitis
- Retinitis

Cardiovascular:
- Myocarditis
- Pericarditis
- Vasculitis

Gastrointestinal:
- Colitis
- Ileitis
- Pancreatitis
- Gastritis

Immune-Related AEs in Phase 3 TNBC Trials With CPI

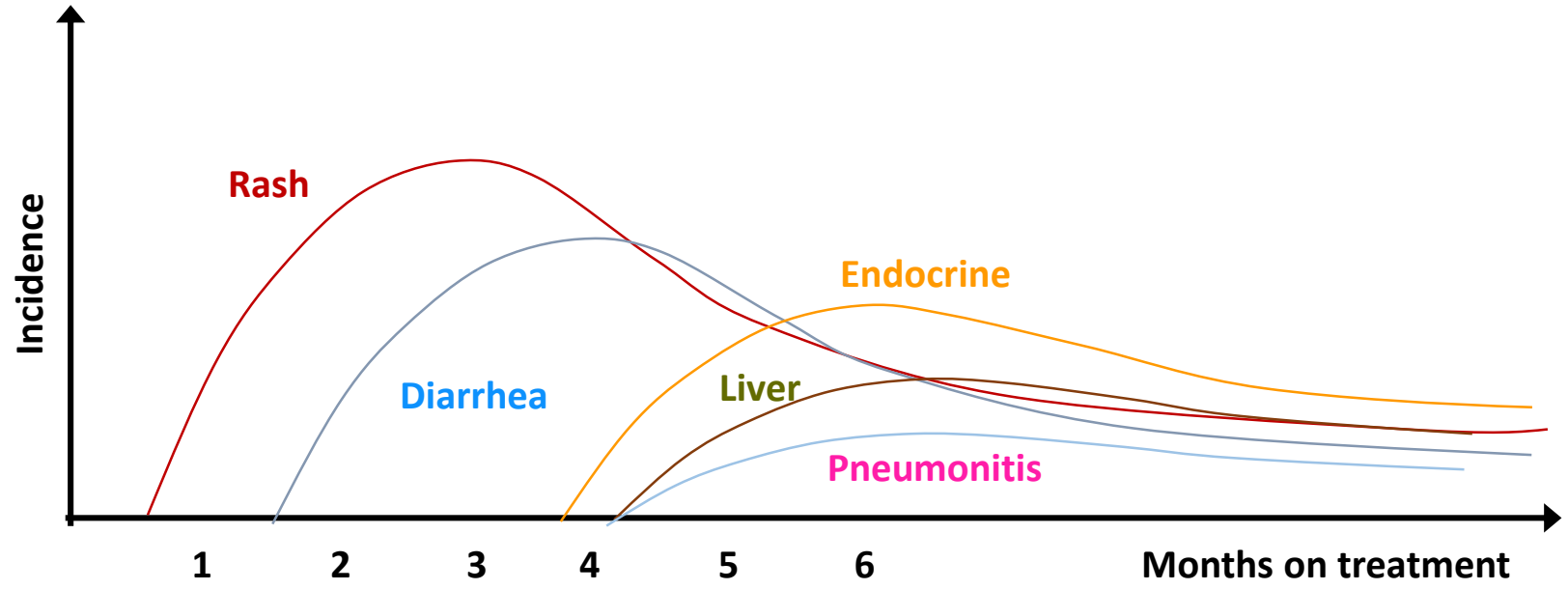


* Above the incidence in the control arm

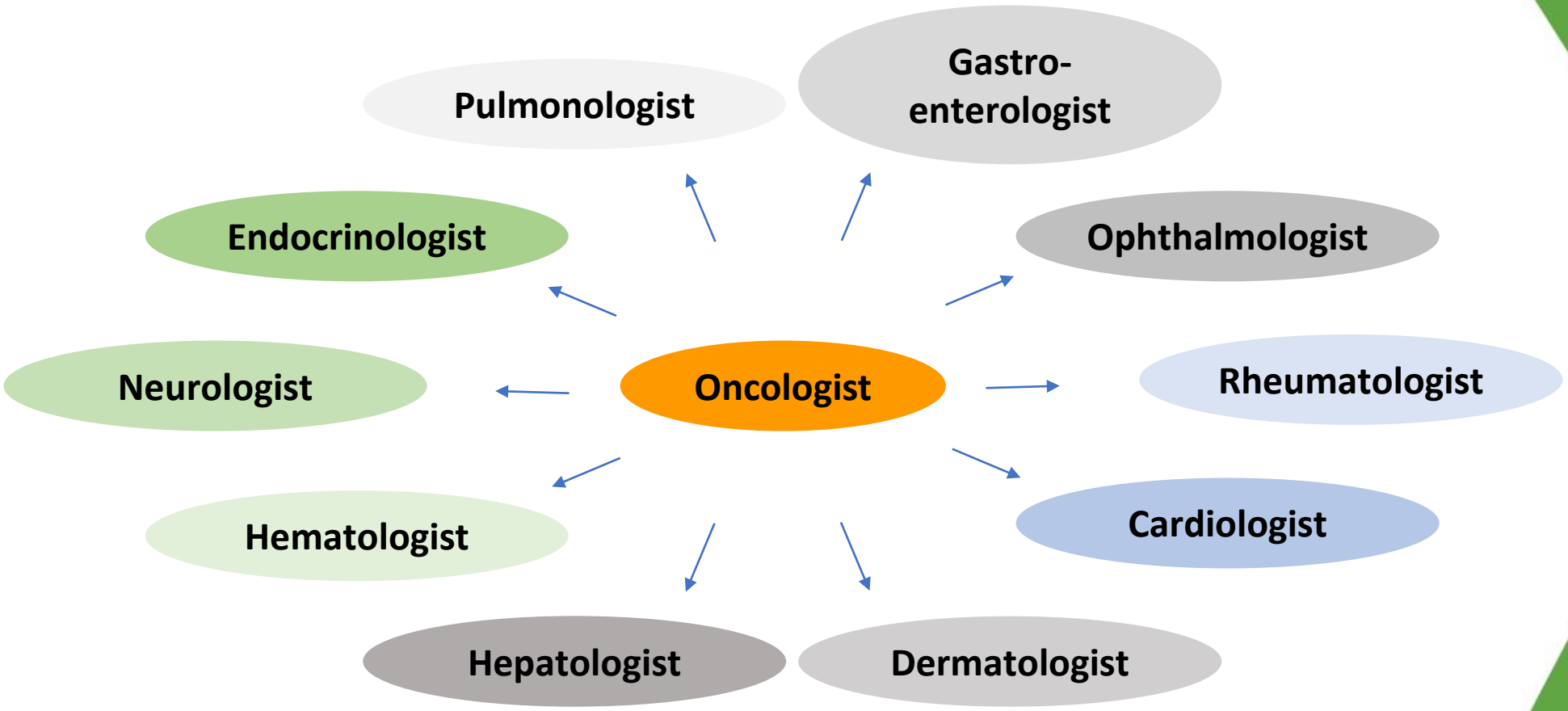
Schmid P, Lancet Oncol 2019

Toxicities With Immune Checkpoint Inhibitors

- Timing can be highly variable
- irAE can occur months or even a year after the end of treatment
- Time course might be even more variable with novel combinations



Multidisciplinary Management Coordinated by Oncologist



Slide credit: clinicaloptions.com

Open access Position article and guidelines

Journal for ImmunoTherapy of Cancer

Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immune checkpoint inhibitor-related adverse events

Julie R Brahmer,[1] Hamzah Abu-Sbeih,[2] Paolo Antonio Ascierto ,[3] Jill Brufsky,[4] Laura C Cappelli,[5] Frank B Cortazar,[6,7] David E Gerber,[8] Lamya Hamad,[9] Eric Hansen,[10] Douglas B Johnson,[11] Mario E Lacouture,[12] Gregory A Masters,[13] Jarushka Naidoo,[1,14] Michele Nanni,[10] Miguel-Angel Perales,[12] Igor Puzanov,[10] Bianca D Santomasso,[15] Satish P Shanbhag,[5,16] Rajeev Sharma,[10] Dimitra Skondra,[17] Jeffrey A Sosman,[18] Michelle Turner,[1] Marc S Ernstoff [19]

Webinar outline

- Development of the guideline
- Toxicity timeframes
- Case 1: Neoadjuvant therapy
- Case 2: First-line metastatic
- Key takeaways

Case 1: Neoadjuvant therapy

- 44 year old woman presents with a newly diagnosed cT2N1 TNBC.
- She currently is a surgical candidate.
- What do you recommend next?

Neoadjuvant Studies: KEYNOTE-522

Eligibility

- Newly diagnosed TNBC (central confirmation)
- T1c N+ or T≥2 N0-2
- PD-L1+ or PD-L1-

Stratification

- T1/T2 vs T3/T4
- N0 vs N+
- Carboplatin Q1W vs Q3W

N = 1,174

R

Neoadjuvant chemo **+ pembrolizumab**

Neoadjuvant chemo **+ placebo**

Surgery

Adjuvant **pembrolizumab** 9 cycles

Adjuvant **placebo** 9 cycles

Within 3-6 weeks

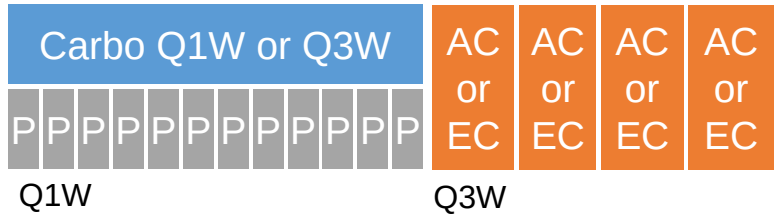
Primary endpoints

- pCR rate (ypT0/Tis ypN0)
- EFS

Secondary endpoints

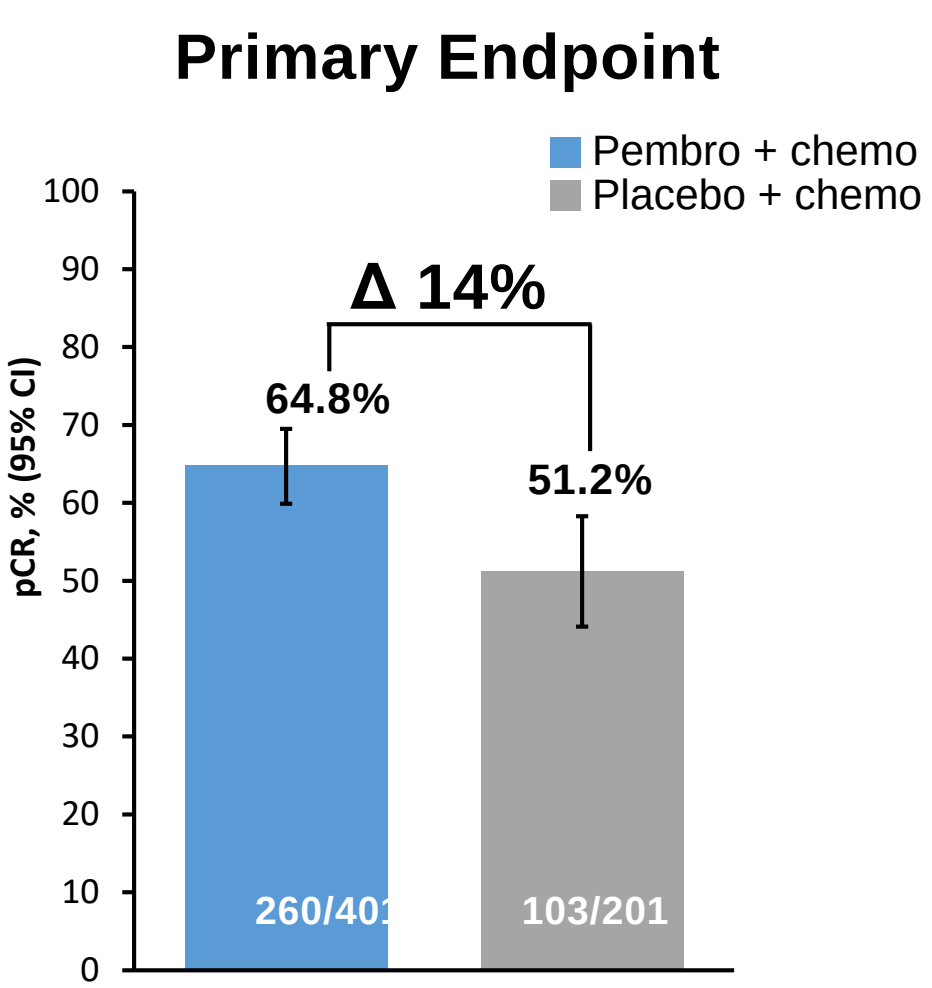
- Alternative pCR rate (ypT0 ypN0)
- pCR rate in PD-L1+
- EFS in PD-L1+
- OS

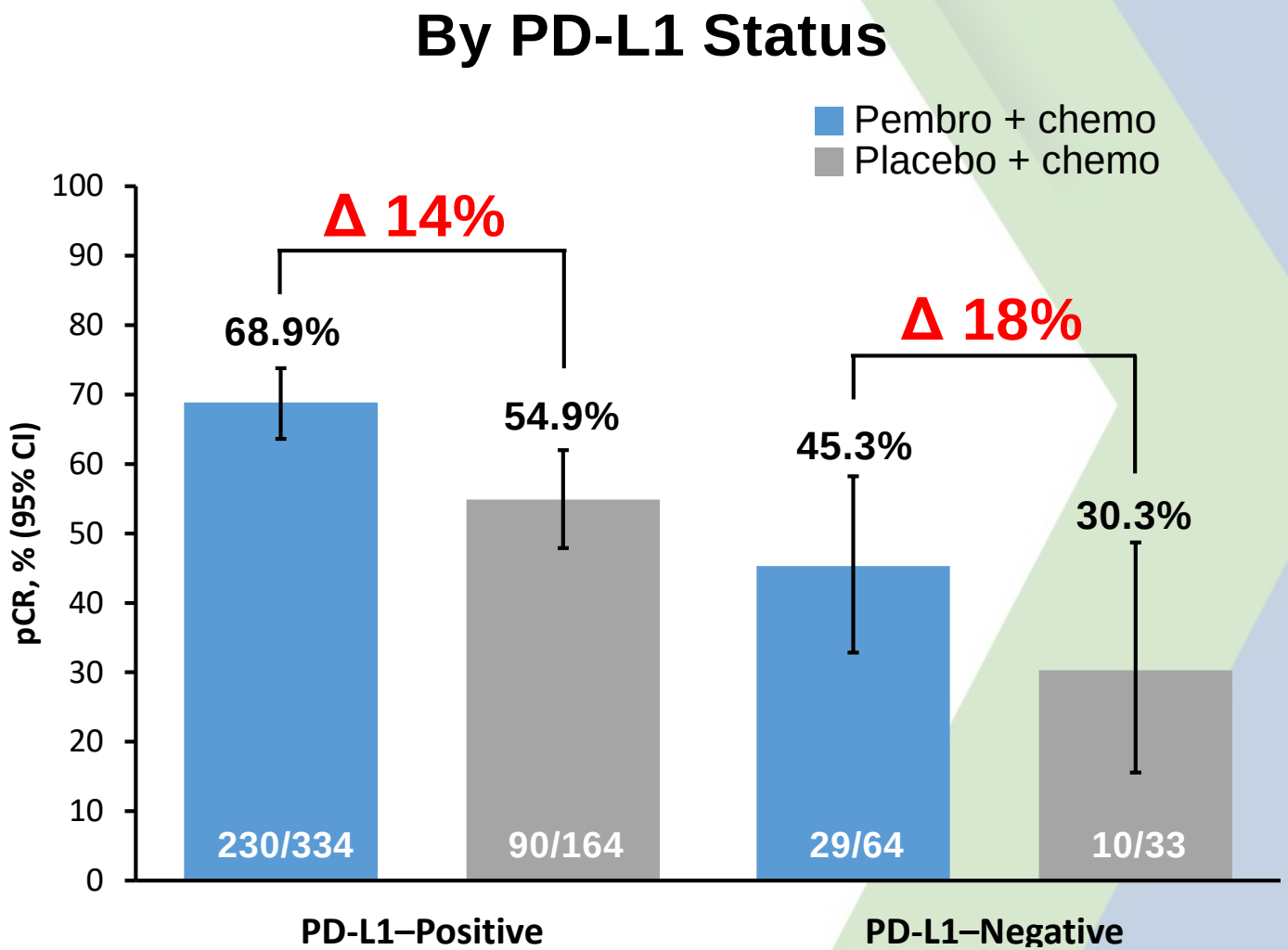
Study Treatment



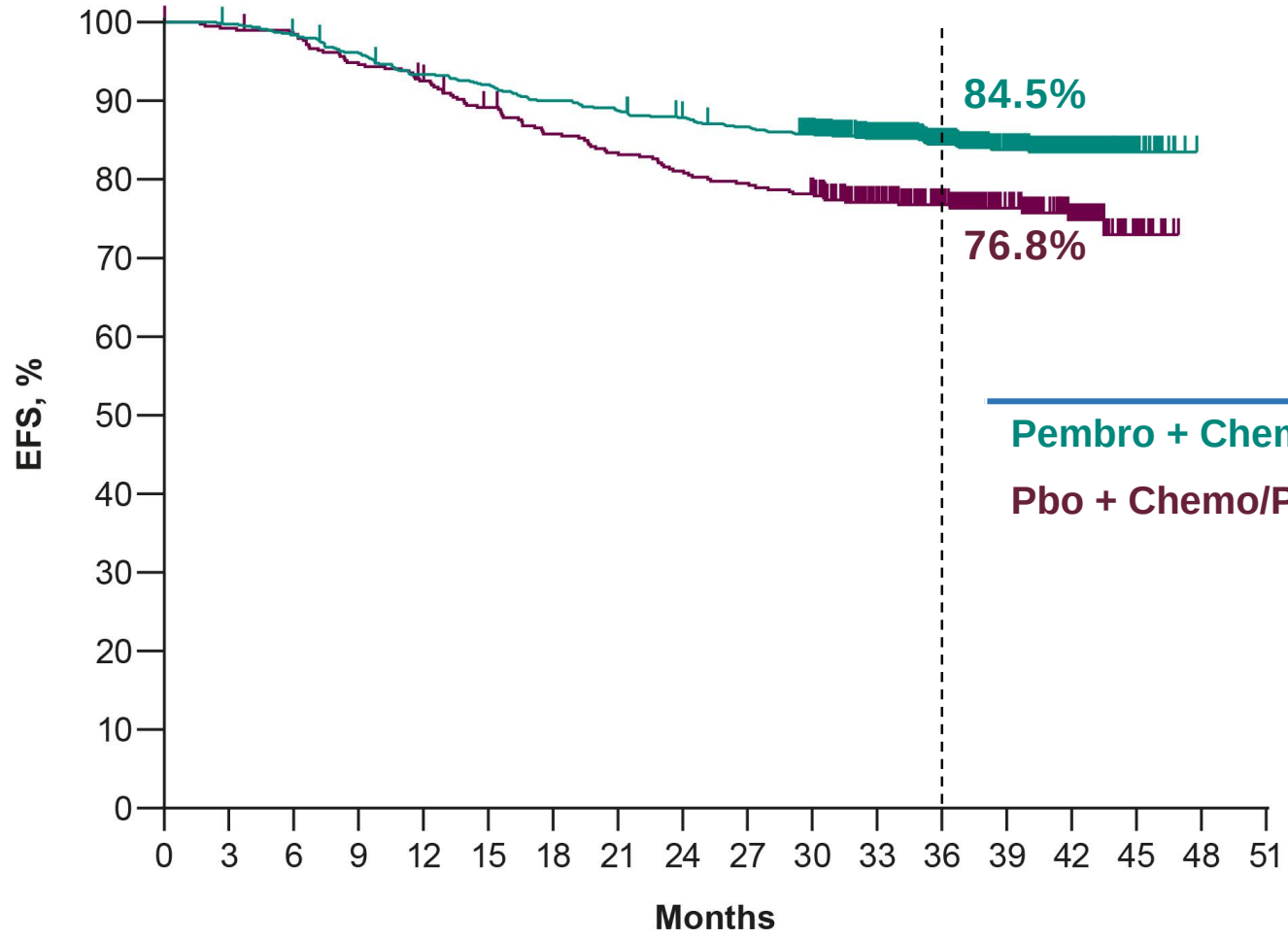
Paclitaxel 80 mg/m^2 IV weekly
Carboplatin weekly (AUC 1.5) or Q3W (AUC5)
Doxorubicin 60 mg/m^2 IV Q3W
(Epirubicin 90 mg/m^2 IV Q3W)
Cyclophosphamide 600 mg/m^2 IV Q3W
Pembrolizumab 200 mg IV Q3W

KEYNOTE-522: pCR at IA1[1]





EFS update at IA4 (39.1mo)



	Events	HR (95% CI)	*P*-value
Pembro + Chemo/Pembro	15.7%	0.63[a]	0.00031[b]
Pbo + Chemo/Pbo	23.8%		

No. at Risk

Pembro + Chemo/Pembro	784	781	769	751	728	718	702	692	681	671	652	551	433	303	165	28	0	0
Pbo + Chemo/Pbo	390	386	382	368	358	342	328	319	310	304	297	250	195	140	83	17	0	0

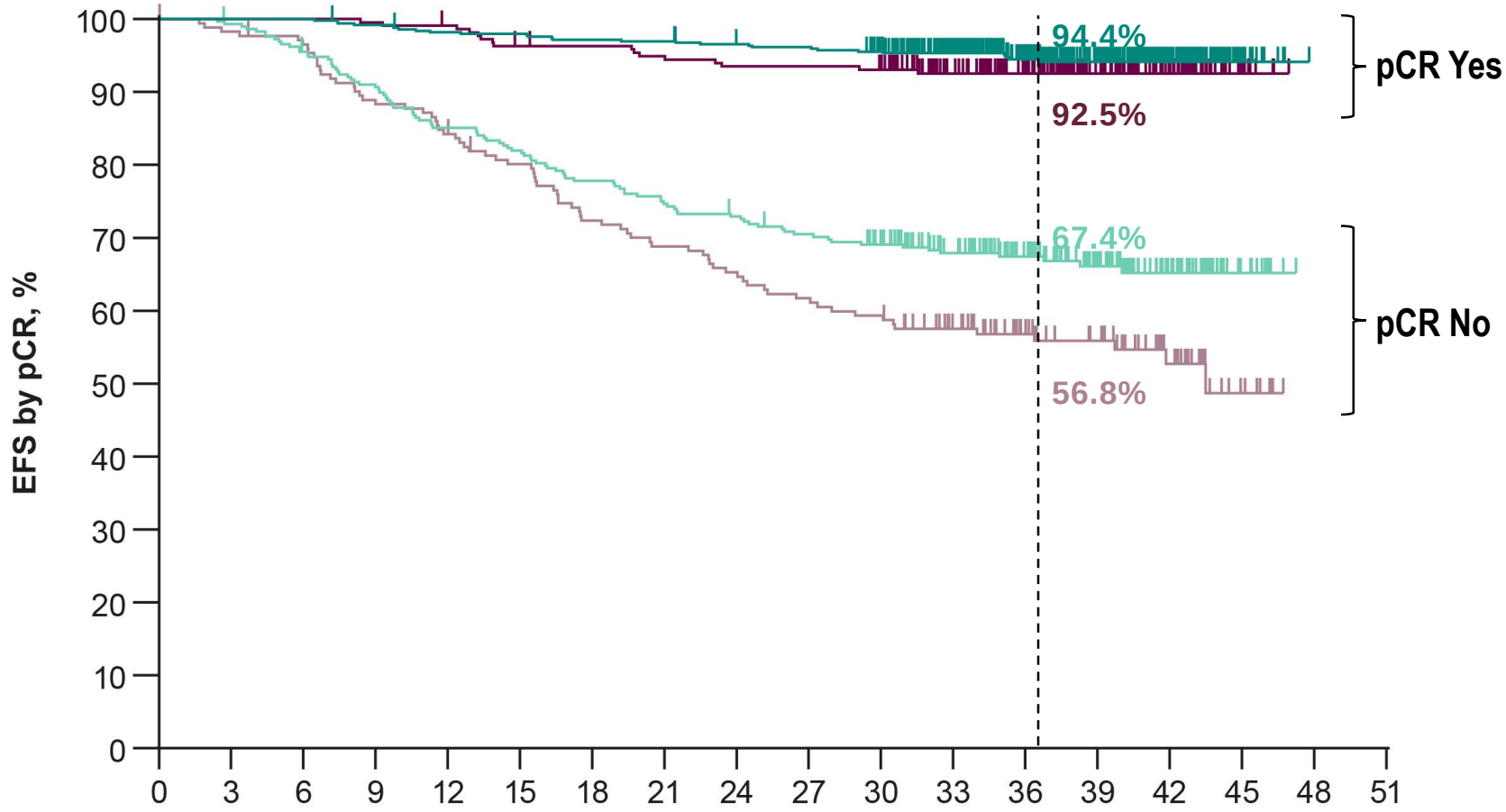
Schmid et al. ESMO Virtual Plenary. Abstract VP7-2021. Presented July 15, 2021.

Summary of First EFS Events by Category

Event	All Subjects, N = 1174	
	Pembro + Chemo/Pembro N = 784	Pbo + Chemo/Pbo N = 390
Any EFS event	**123 (15.7%)**	**93 (23.8%)**
Progression of disease that precludes definitive surgery	14 (1.8%)	15 (3.8%)
Local recurrence[a]	28 (3.6%)	17 (4.4%)
Distant recurrence	**60 (7.7%)**	**51 (13.1%)**
Secondary primary malignancy[b]	6 (0.8%)	4 (1.0%)
Death	15 (1.9%)	6 (1.5%)

Schmid et al. ESMO Virtual Plenary. Abstract VP7-2021. Presented July 15, 2021.

EFS by pCR (ypT0/Tis ypN0)

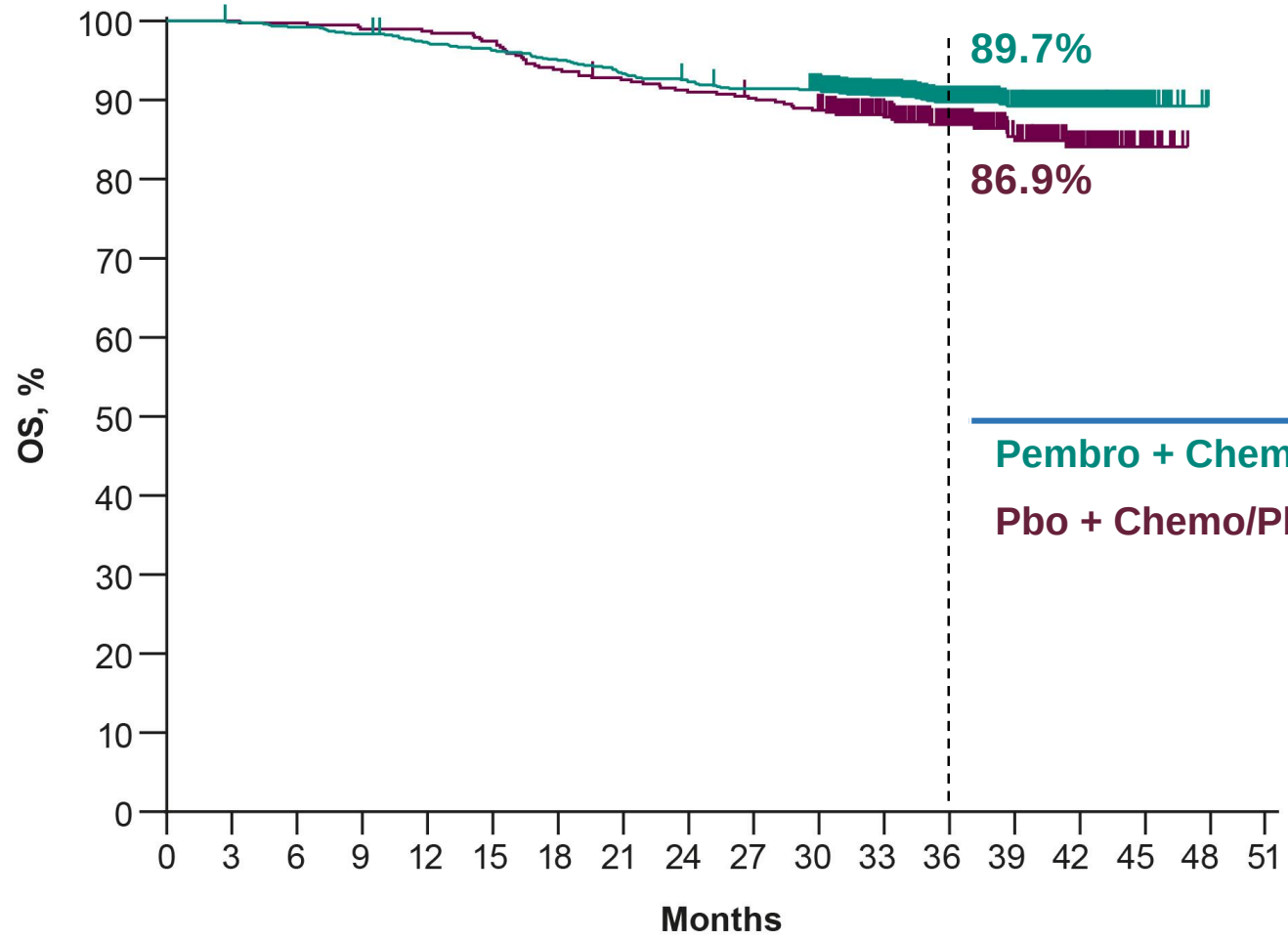


No. at Risk																		
Pembro + Chemo/Pembro Responder	494	494	494	489	483	482	478	477	472	470	460	387	307	220	122	18	0	0
Pbo + Chemo/Pbo Responder	217	217	217	216	214	207	206	203	200	200	197	165	130	87	56	9	0	0
Pembro + Chemo/Pembro Non-Responder	290	287	275	262	245	236	224	215	209	201	192	164	126	83	43	10	0	0
Pbo + Chemo/Pbo Non-Responder	173	169	165	152	144	135	122	116	110	104	100	85	65	53	27	8	0	0

108/201

Schmid et al. ESMO Virtual Plenary. Abstract VP7-2021. Presented July 15, 2021.

Overall Survival



	Events	HR (95% CI)	*P*-value
Pembro + Chemo/Pembro	10.2%	0.72[a] (0.51-1.02)	0.03214[b]
Pbo + Chemo/Pbo	14.1%		

No. at Risk

Pembro + Chemo/Pembro	784	782	777	770	759	752	742	729	720	712	701	586	461	323	178	30	0	0
Pbo + Chemo/Pbo	390	390	389	386	385	380	366	360	354	350	343	286	223	157	89	17	0	0

Schmid et al. ESMO Virtual Plenary. Abstract VP7-2021. Presented July 15, 2021.

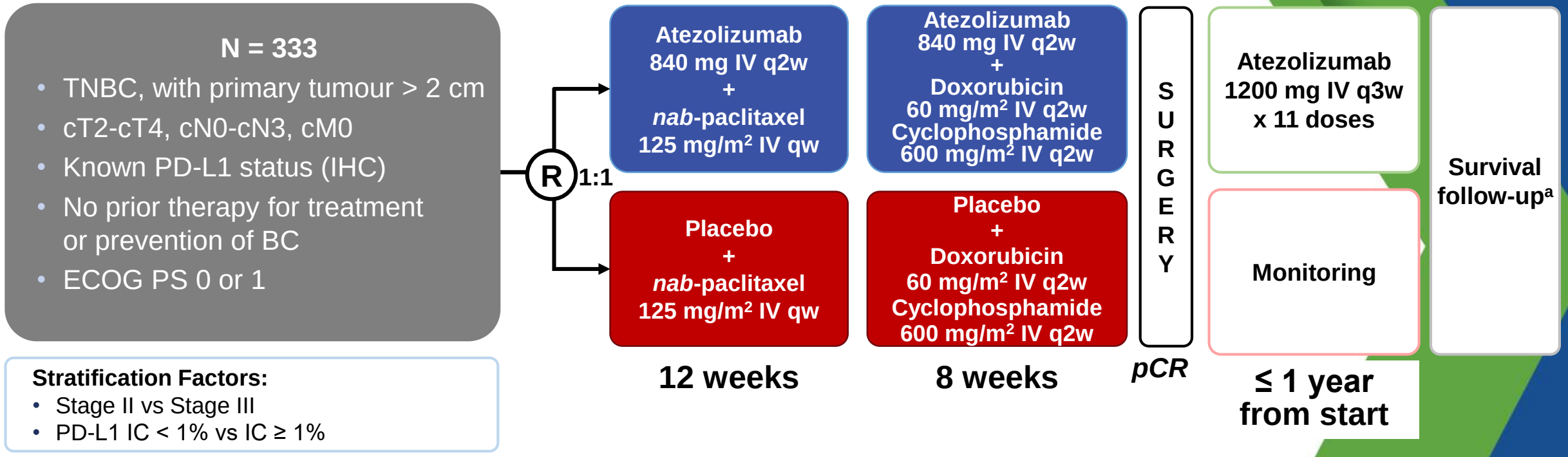
FDA-Approval[1]

- On July 27, 2021, the FDA approved pembrolizumab for high-risk early-stage TNBC with chemotherapy as neoadjuvant treatment and then continued as a single agent as adjuvant treatment after surgery

- Based on KEYNOTE-522, the indication for palliative pembrolizumab was converted from accelerated to full approval

IMpassion031: Phase III atezolizumab neoadjuvant study in eTNBC

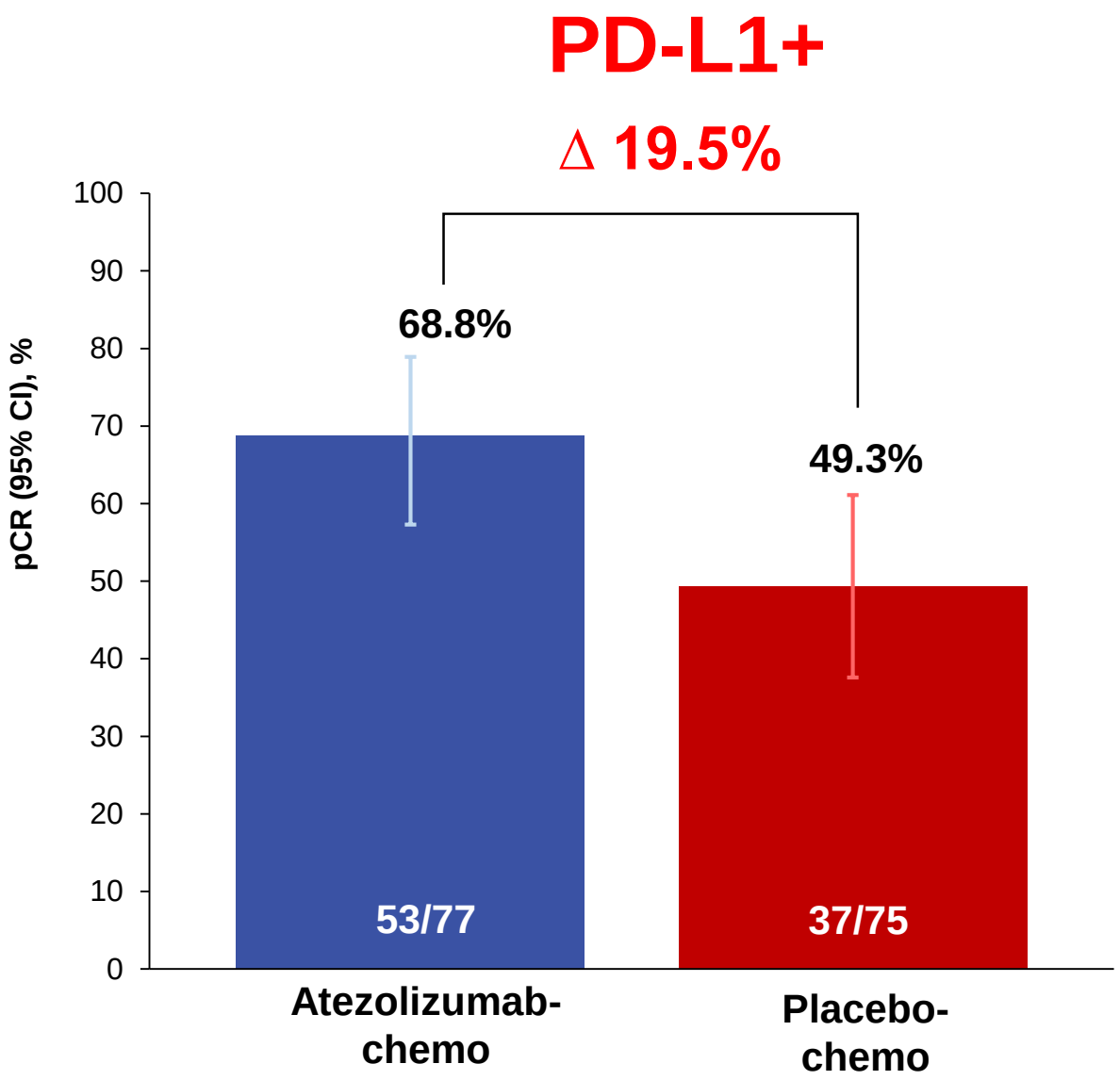
A randomized, multicenter, international, double-blind, placebo-controlled trial

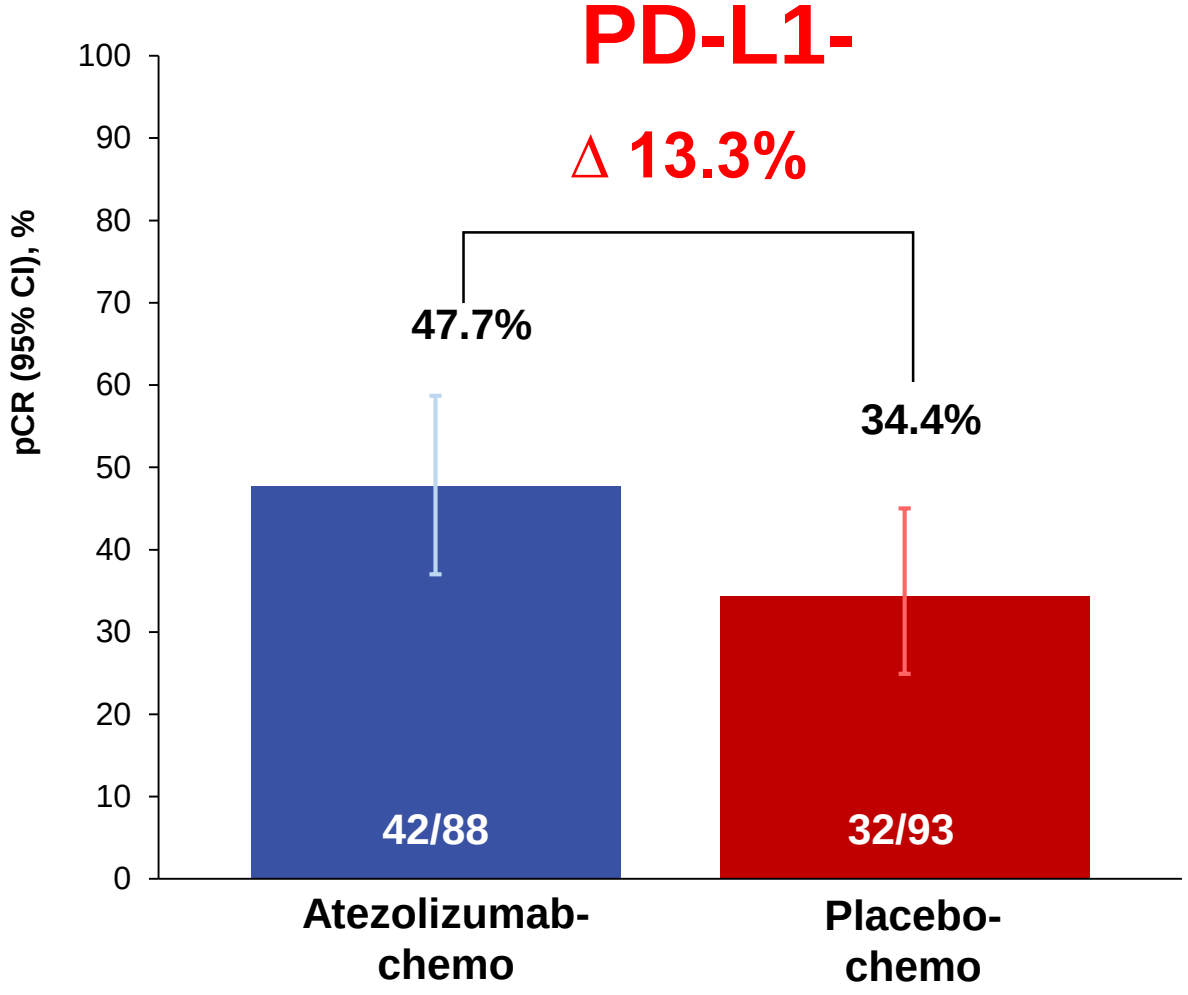


Co-primary endpoints: Pathologic complete response (pCR, ypT0/is ypN0) in ITT and PD-L1–positive (IC ≥ 1%) subpopulation

Secondary endpoints: EFS, DFS, and OS in ITT and in PD-L1–positive subpopulation, safety, PROs

Co-primary endpoint pCR by PD-L1 status





Harbeck et al ESMO 2020
Mittendorf et al. 2020 Oct 10;396(10257):1090-1100.

Adjuvant Studies: IMpassion030

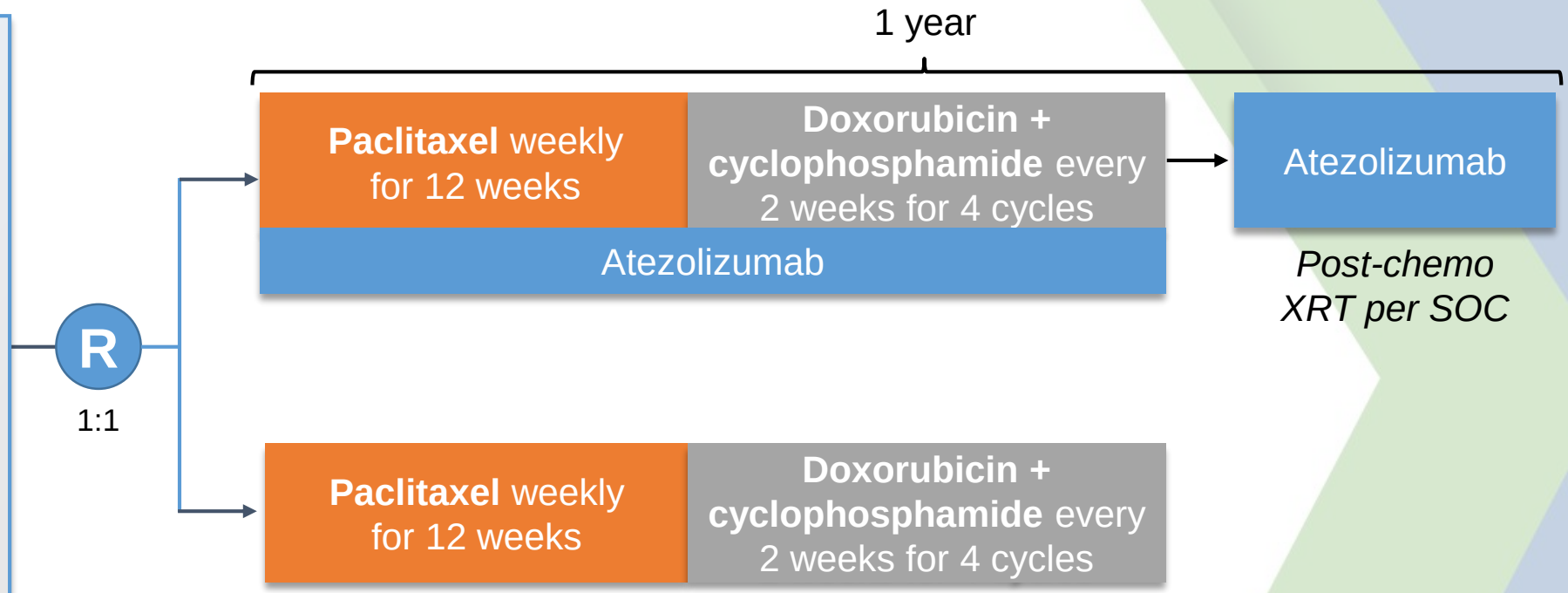
Eligibility

- **Adequately excised primary invasive TNBC (stage II/III)** 50:50 node negative/positive–enriched population

Stratification

- Axillary nodal status (0 vs 1-3 vs ≥4 positive lymph nodes)
- Surgery (breast conserving vs mastectomy)
- PD-L1 IC0 vs IC1/2/3

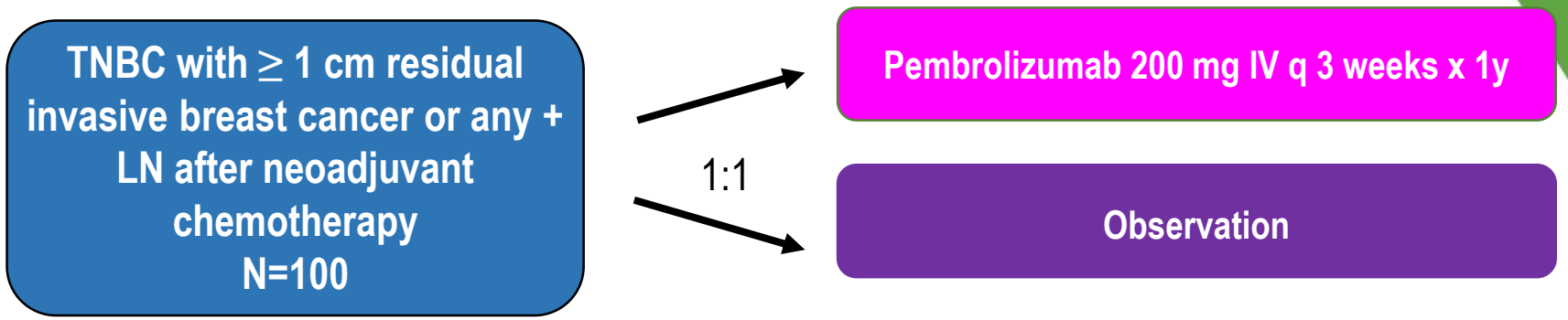
N = 2,300



- **Primary endpoint:** iDFS in ITT
- **Secondary endpoints:** iDFS PD-L1 IC1/2/3, OS, RFI, distant RFI, safety, and health-related QoL

Co-PIs: Ignatiadis, McArthur, Saji

Post NAC Residual Disease: SWOG 1418



- **Registration:**
  - Central PD-L1 testing
- **Stratification:**
  - Nodal stage ypNo vs ypN+
  - Residual tumor ≥2 vs < 2cm
  - PD-L1 pos vs neg
  - Prior adjuvant chemo yes vs no

- **Hypothesis:**
  - Pembrolizumab reduces IDFS by 33% c/w observation alone
- **Primary Endpoint:**
  - Invasive DFS in PD-L1-positive and overall cohort
- **Secondary Endpoints:**
  - Toxicity
  - OS
  - DRFS
  - QOL (PROMIS, PRO-CTCAE forms, inflammatory markers)
  - Tissue banking

PI Lajos Pusztai. US National Library of Medicine. Clinicaltrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT02954874. Accessed December 13, 2017.

Case 1, continued

- She receives neoadjuvant pembrolizumab + paclitaxel x 12 cycles followed by ddAC
- Post treatment- reveals a pCR
- Post-operatively, she develops confusion and is unable to answer questions appropriately.

- A brain MRI is unremarkable?
- What are your next steps?

Case 1, continued

- CMP, cortisol, ACTH, FSH, LH, TSH, T4
- Morning serum cortisol = 1.8 mcg/dL (Normal 10–20 mcg/dL)
- Plasma ACTH = 21 pg/mL (Normal 20–52 pg/mL)
- Very low cortisol, low-to-normal ACTH
- DS is diagnosed with secondary adrenal insufficiency (hypophysitis) and receives hydrocortisone indefinitely

Primary adrenal insufficiency

- Evaluate morning cortisol and ACTH levels
- Comprehensive metabolic panel (Na, K, CO^2, glucose)

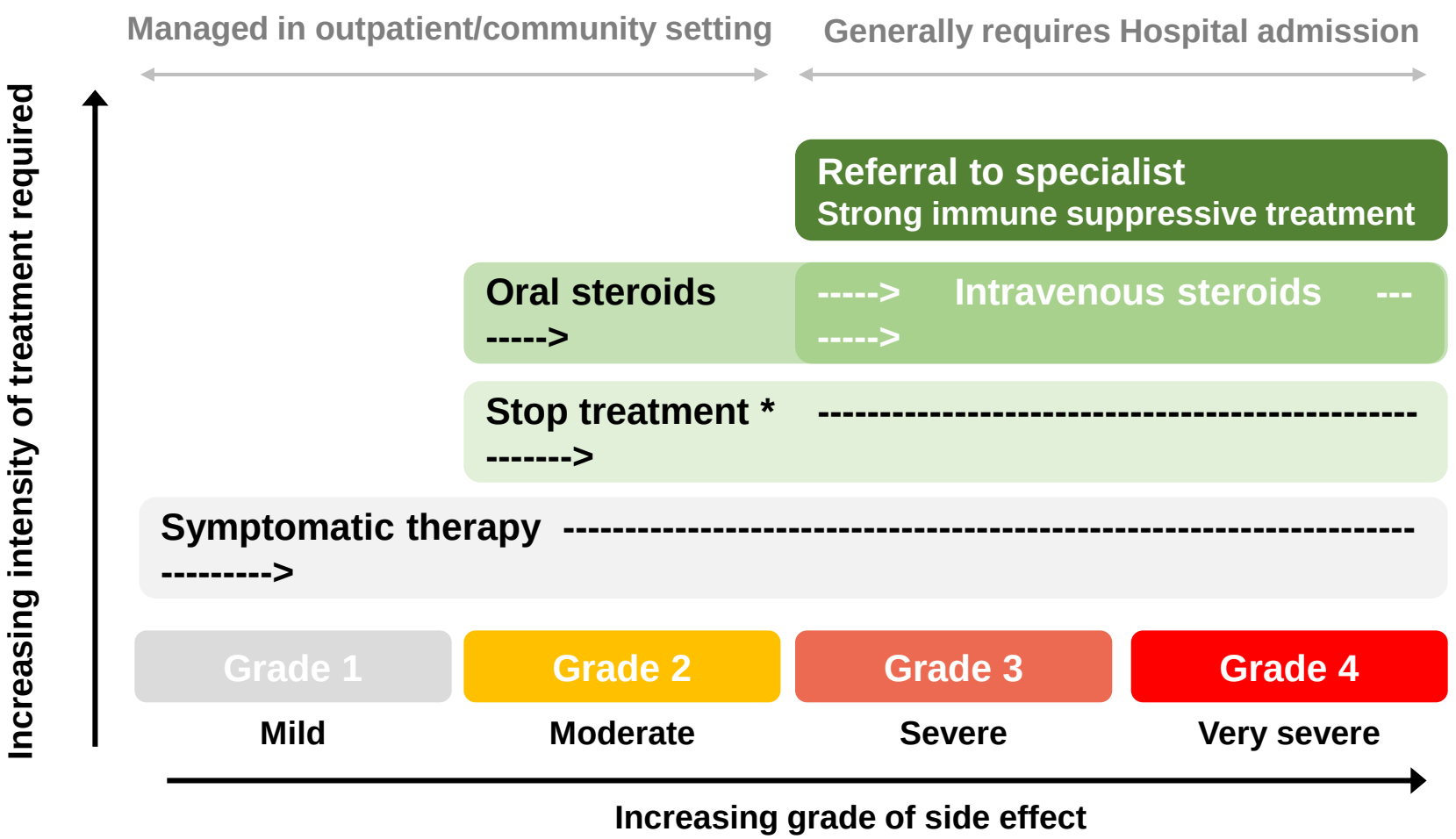
Hypophysitis

- Evaluate
  - Morning cortisol and ACTH
  - FSH, LH, TSH, free T4, testosterone in men, estrogen in premenopausal women
- MRI brain ± contrast with pituitary/sellar cuts, if symptomatic

Slide credit: clinicaloptions.com

- Majority of irAEs are mild to moderate
- Severity can be asymptomatic to life-threatening; prompt recognition
  is crucial
- Most reversible with steroids; some require discontinuation of therapy
- Important to educate care team, patient, and caregivers on signs and symptoms of irAEs

Brahmer. 2018;36:1714. Postow. NEJM. 2018;378:158. Puzanov. JIC. 2017;5:95. Michot. EJC. 2016;54:139.



Steroids (PO/IV): 1-2 mg/kg/d prednisone or equivalent, slow taper over 4-6/52

*** For some AEs, treatment can be restarted after resolution (e.g. rash); CPI generally continued with endocrinopathies once managed**

Adapted from Champiat. ESMO Patient Guide Series.

Slide credit: clinicaloptions.com

Webinar outline

- Development of the guideline
- Toxicity timeframes
- Case 1: Neoadjuvant therapy
- Case 2: First-line metastatic
- Key takeaways

Case 2: First-line metastatic

- 41 year old woman with a *BRCA*1 mutation was treated with ddAC and weekly paclitaxel 2 years ago for an early stage TNBC
- She now presents with new cough and CT chest identifies multiple new lung nodules
- Biopsy of a 1.5 cm RLL nodule is consistent with metastatic TNBC
- What should you do next?

Case 2: First-line metastatic, continued

- You check PD-L1 status
  - What should you check?

IMpassion130

IMpassion130 (NCT02425891): A Global, Randomized, Double-Blind, Phase 3 Study of Atezolizumab + Nab-Paclitaxel vs Placebo + Nab-Paclitaxel in Treatment-Naïve Locally Advanced or Metastatic TNBC

- Previously untreated metastatic or inoperable locally advanced TNBC[a]
- ECOG PS 0-1

Stratification

- Prior taxane use
- Liver metastases
- **PD-L1 on IC[b]**

N = 902

Double blind
no crossover

R

1:1

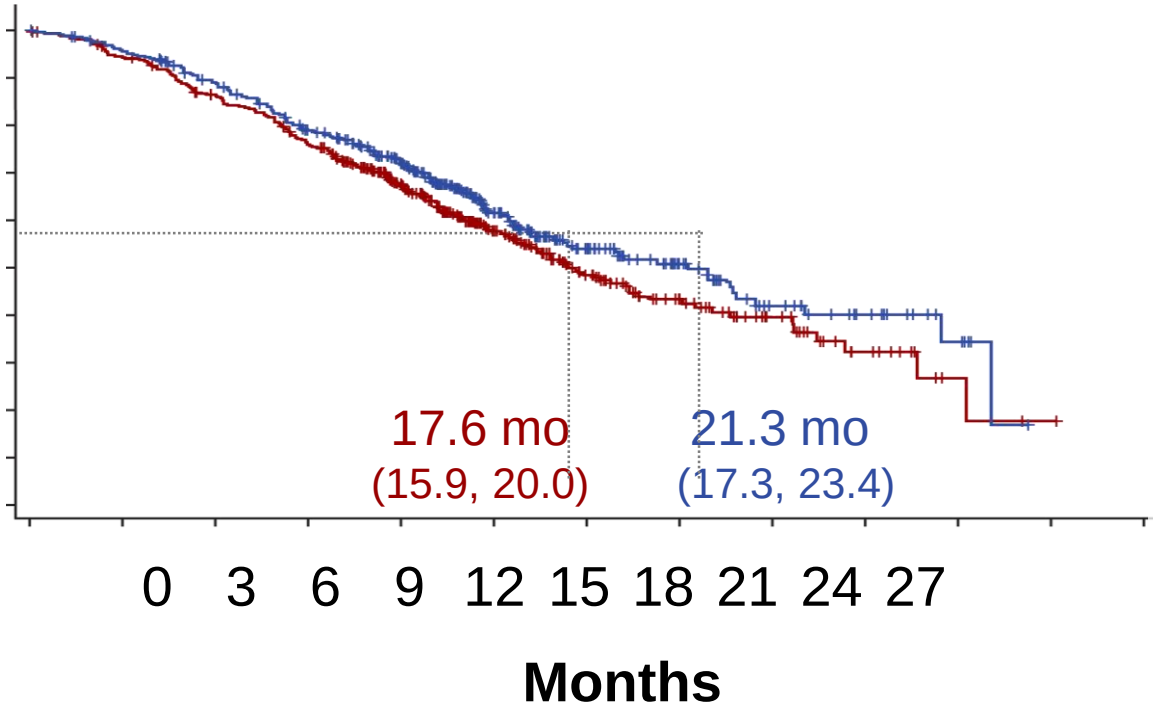
Atezolizumab 840 mg IV on d 1 and 15
+ nab-P 100 mg/m² IV on d 1, 8, and 15
of 28-d cycle until RECIST v1.1 PD
ITT population: n = 451
PD-L1 IC+ patients: n = 185 (41%)

Placebo 840 mg IV on d 1 and 15
+ nab-P 100 mg/m² IV on d 1, 8, and 15
of 28-d cycle until RECIST v1.1 PD
ITT population: n = 451
PD-L1 IC+ patients: n = 184 (41%)

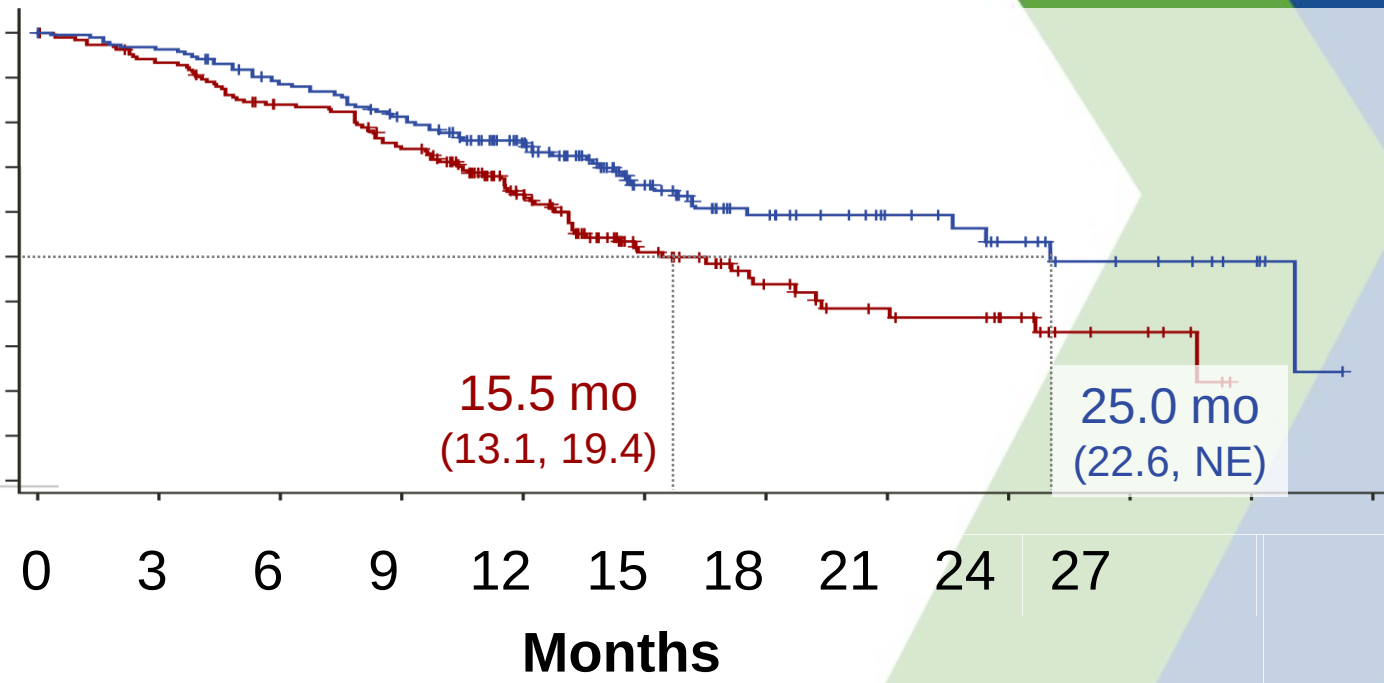
- **Co-primary endpoints:** PFS and OS in the ITT and PD-L1 populations
- **Key secondary endpoints:** ORR, DOR, and safety

Interim OS Analysis

ITT



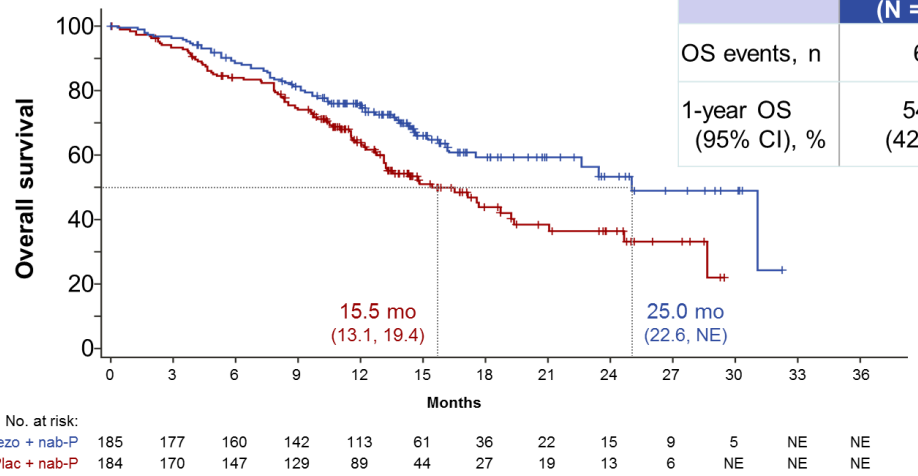
PD-L1+



Schmid P et al. *N Engl J Med*. 2018;379:2108-2121.

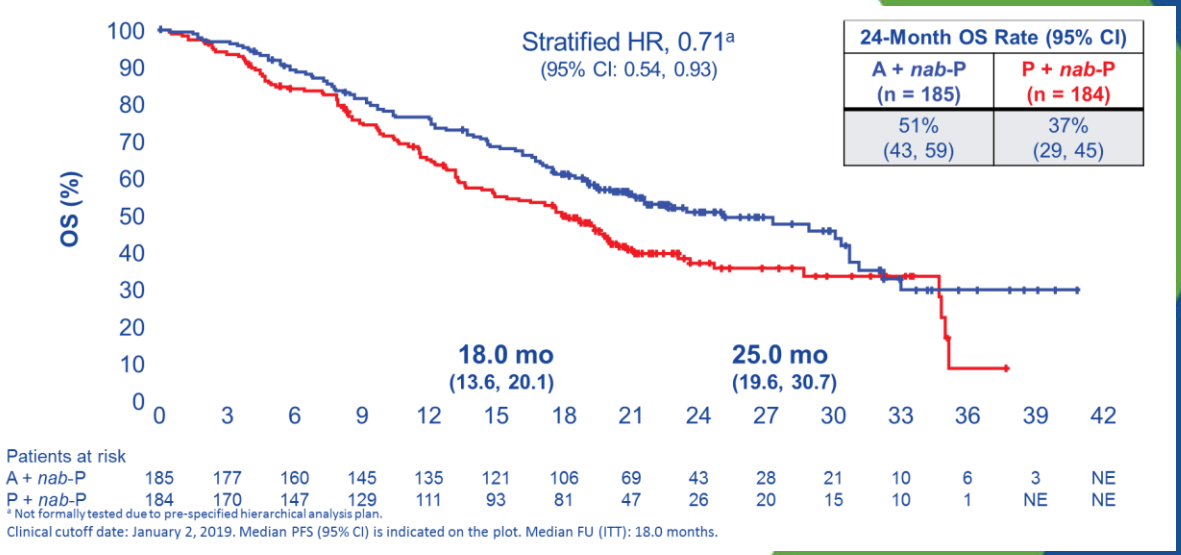
IMpassion 130: Overall Survival

Interim OS in PD-L1+ Group



	Atezo + nab-P (N = 185)	Plac + nab-P (N = 184)
OS events, n	64	88
1-year OS (95% CI), %	54% (42, 65)	37% (26, 47)

ASCO 2019 OS Update



24-Month OS Rate (95% CI)	
A + *nab*-P (n = 185)	P + *nab*-P (n = 184)
51% (43, 59)	37% (29, 45)

Schmid P, et al. *NEJM* 2018;379:2108-2121
Schmid P, et al. ASCO 2019

FDA-Approval

- On 3/8/19, the FDA granted accelerated approval to atezolizumab in combination with protein-bound paclitaxel for patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥1% of the tumor area), as determined by an FDA-approved test.

FDA-Approval

- On 08/27/21, Roche withdrew the indication for atezolizumab for mTNBC
- Continued approval was contingent upon IMpassion131 trial meeting the primary PFS end point
- A potential alternative pre-market requirement is being explored

KEYNOTE-355 Study Design (NCT02819518)

- paclitaxel,
- nab-paclitaxel
- gemcitabine/carboplatin

Key Eligibility Criteria

- Age ≥18 years
- Central determination of TNBC and PD-L1 expression
- Previously untreated locally recurrent inoperable or metastatic TNBC
- Completion of treatment with curative intent ≥6 months prior to first disease recurrence
- ECOG performance status 0 or 1
- Life expectancy ≥12 weeks from randomization
- Adequate organ function
- No systemic steroids
- No active CNS metastases
- No active autoimmune disease

Stratification Factors:

- Chemotherapy on study (taxane vs gemcitabine/carboplatin)
- PD-L1 tumor expression (CPS ≥1 vs CPS <1)
- Prior treatment with same class chemotherapy in the neoadjuvant or adjuvant setting (yes vs no)

Baseline Characteristics, ITT

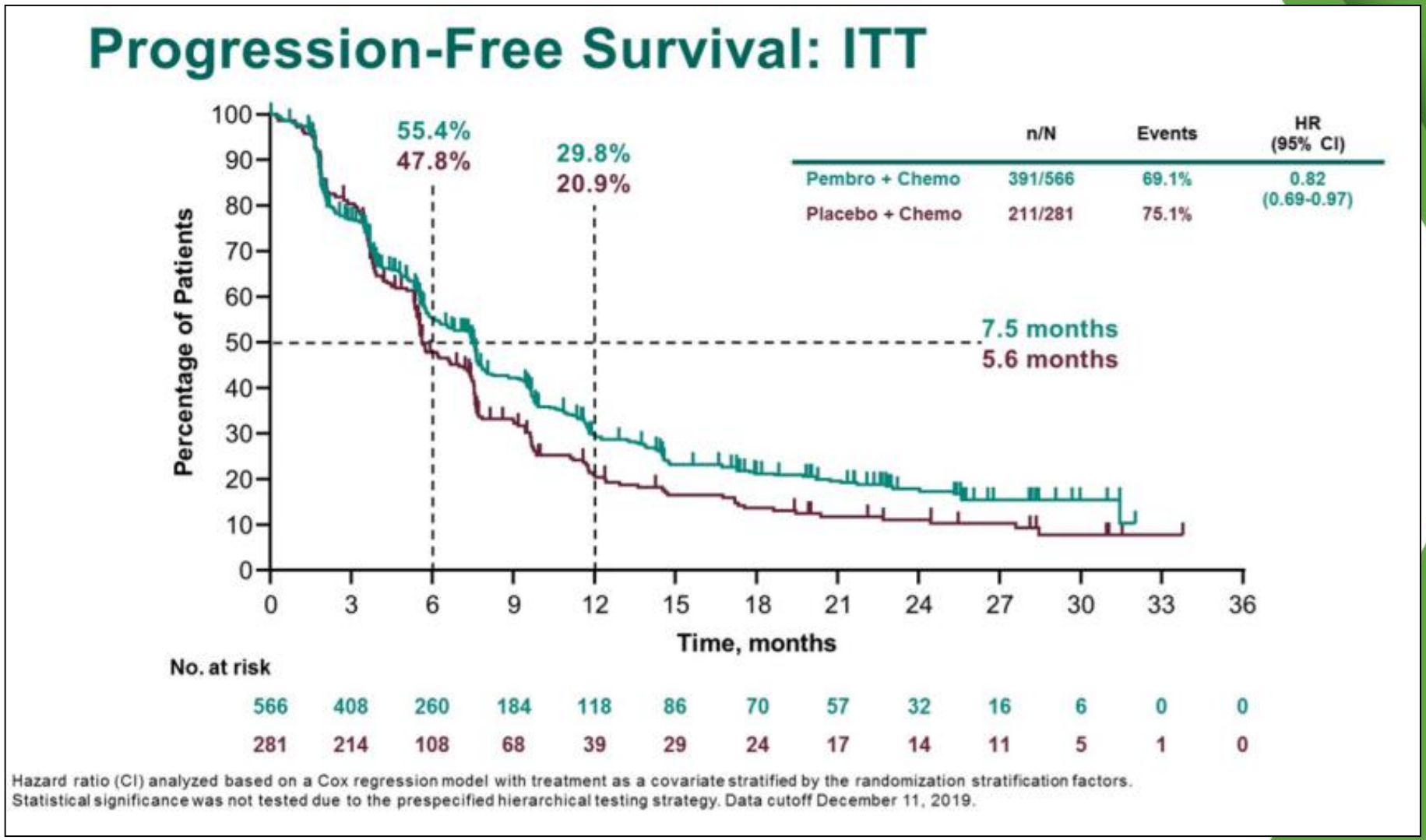
Baseline Characteristics, ITT

Characteristic, n (%)	All Subjects, N = 847	
	Pembro + Chemo N = 566	Placebo + Chemo N = 281
Age, median (range), yrs	53 (25-85)	53 (22-77)
ECOG PS 1	232 (41.0)	108 (38.4)
PD-L1–positive CPS ≥1	425 (75.1)	211 (75.1)
PD-L1–positive CPS ≥10	220 (38.9)	103 (36.7)
Chemotherapy on study		
Taxane	255 (45.1)	127 (45.2)
Gemcitabine/Carboplatin	311 (54.9)	154 (54.8)
Prior same-class chemotherapy		
Yes	124 (21.9)	62 (22.1)
No	442 (78.1)	219 (77.9)
Disease-free interval		
de novo metastasis	167 (29.5)	84 (29.9)
<12 months	126 (22.3)	50 (17.8)
≥12 months	270 (47.7)	147 (52.3)

Data cutoff date: December 11, 2019.

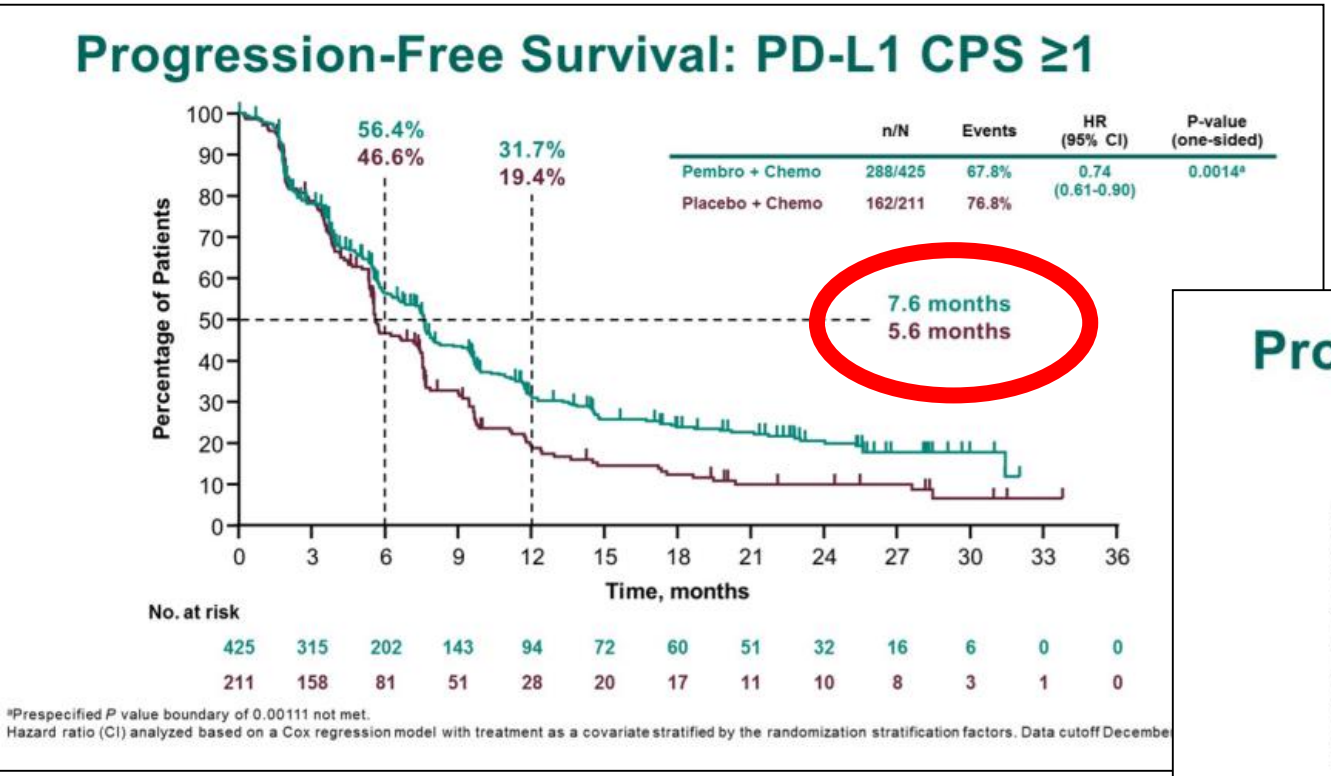
Cortes J et al. ASCO 2020. Abstract 1000.

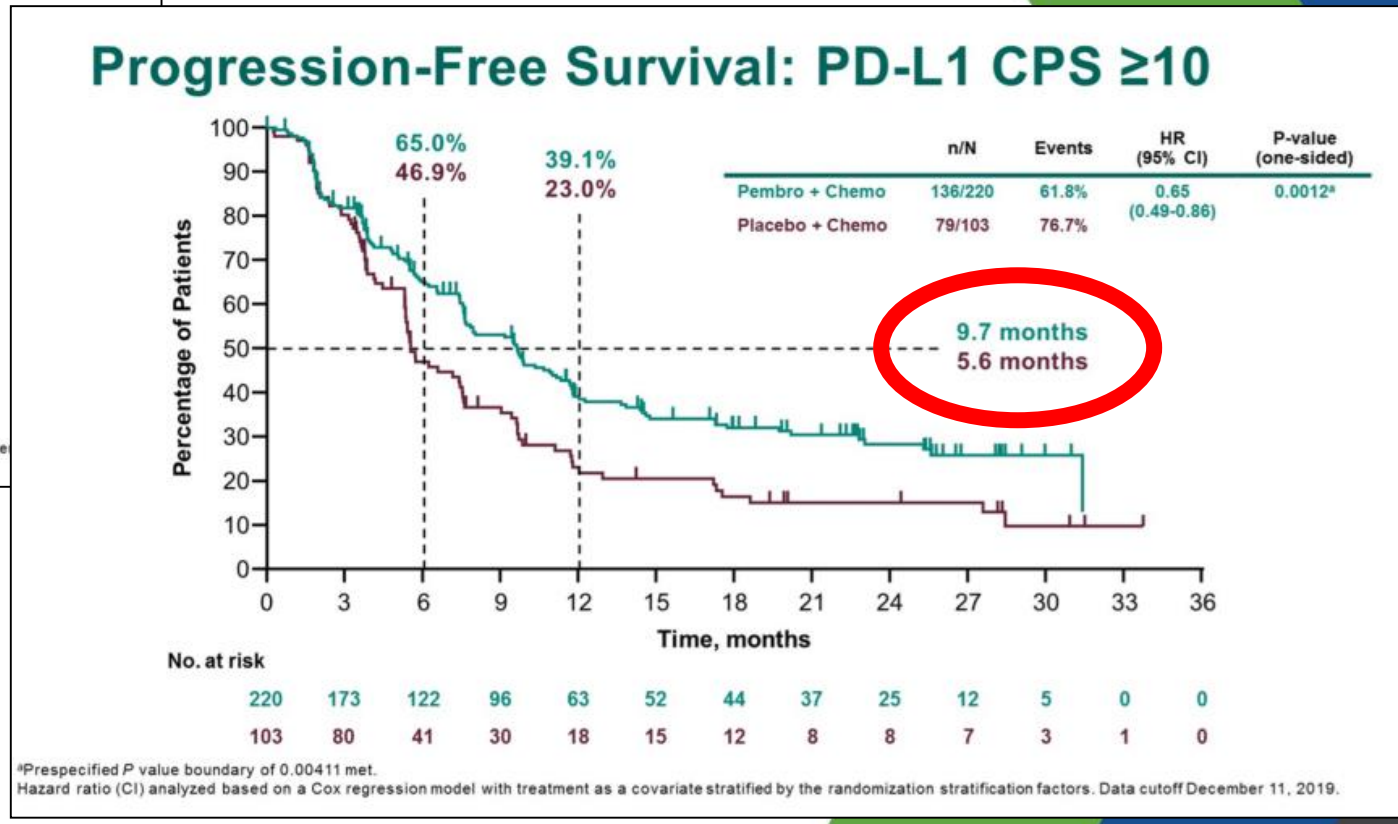
KEYNOTE-355: PFS



Cortes J et al. ASCO 2020. Abstract 1000.

KEYNOTE-355: PFS



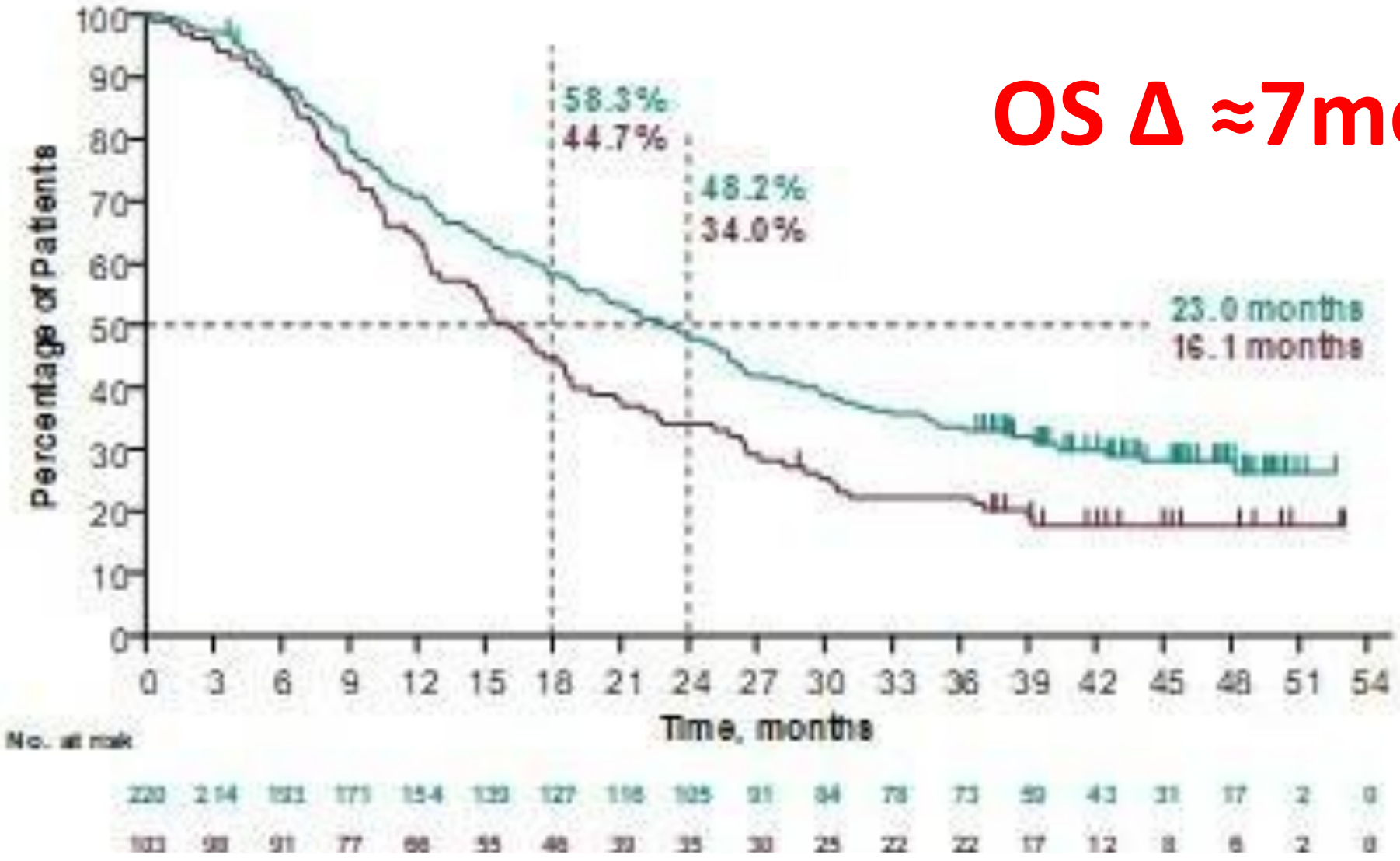


Cortes J et al. ASCO 2020. Abstract 1000.

FDA-Approval[1]

- On 11/13/20, the FDA granted accelerated approval to **pembrolizumab** in combination with chemotherapy for patients with unresectable or metastatic TNBC whose tumors express **PD-L1 (CPS ≥10)** as determined by an FDA-approved test.

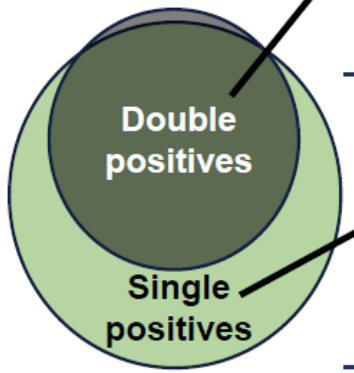
Overall Survival: PD-L1 CPS ≥10



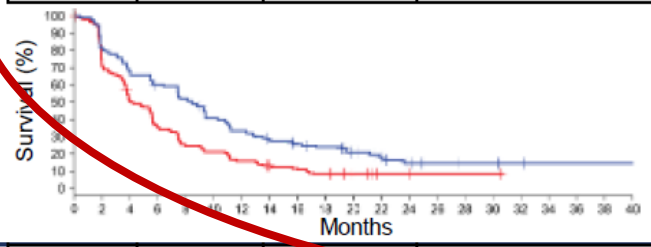
OS Δ ≈7mo

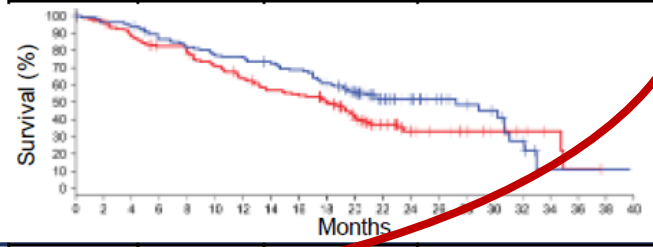
Cortes et al. Abstract LBA16, ESMO 2021

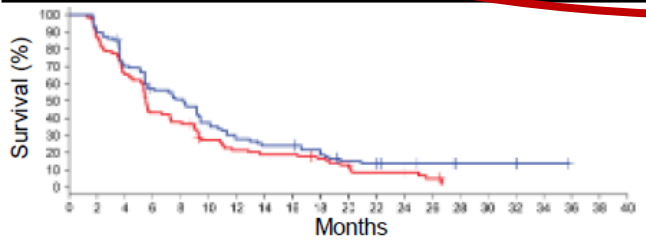
IMpassion130 PD-L1 Analysis

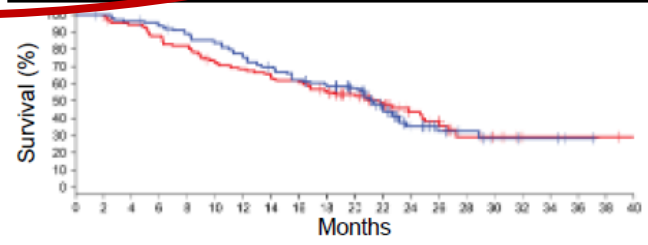


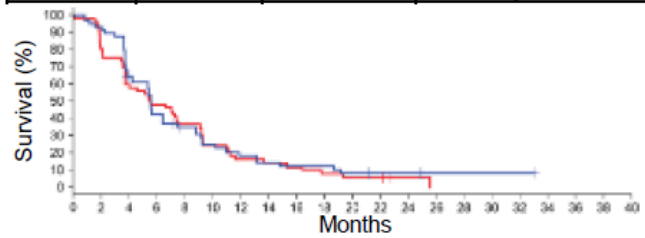
Population	PFS				OS			
	Median PFS, mo			HR (95% CI)	Median OS, mo			HR (95% CI)
	A + nP	P + nP	Δ		A + nP	P + nP	Δ	
SP142+ 22C3+ (45%; 279/614)	8.3	3.9	4.4	0.60 (0.46, 0.78)	27.3	18.0	9.3	0.71 (0.52, 0.98)
SP142- 22C3+ (36%; 218/614)	7.3	5.6	1.7	0.81 (0.61, 1.09)	21.3	21.8	−0.5	0.92 (0.64, 1.31)
SP142- 22C3- (18%, 111/614)	5.5	5.6	−0.1	1.00 (0.66, 1.51)	14.7	19.6	−4.9	1.08 (0.67, 1.76)

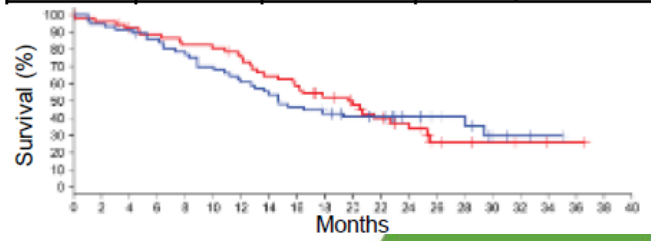












Rugo H, et al. ESMO 2019. Abs LBA20.

Which PD-L1 Assay Should I Use?

Atezolizumab[a]

SP142

Pembroluzimab[b]

TMB > 10
MSI-H/dMMR
CPS* score >10

$$^{*}\text{Combined Positive Score} = \frac{\text{\# of PD–L1+ staining cells (tumor cells, lymphocytes, macrophages}}{\text{total number of viable tumor cells}} x\ 100$$

- a. Atezolizumab [PI]. Approved 2016. Revised March 2019; b. Pembroluzumab [PI]. Approved 2014. Revised November 2020.

Case 2: First-line metastatic- continued

- She has a mild rash and call your office to get instructions

Metastatic TNBC with lung & LN metastases

Paclitaxel + anti-PD/PD-L1

03/2018

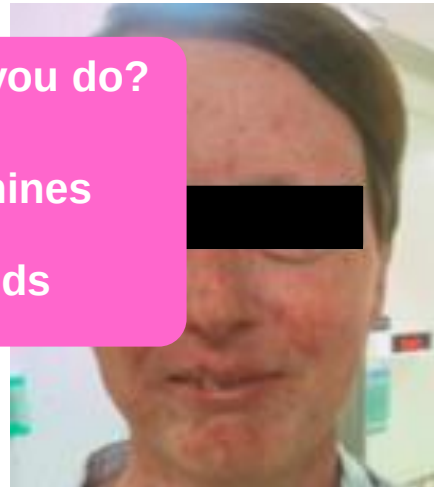
What would you do?

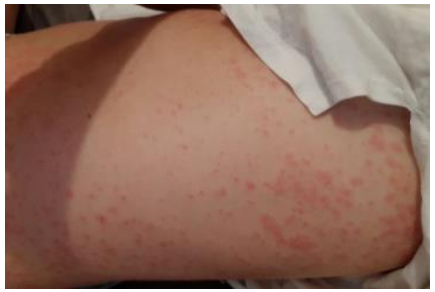
1.
2. Antihistamines
3. Topical steroids
4.

After 3 weeks patient presents with G1 rash

What would you do?

2. Antihistamines
4. Oral steroids





2 days later rash deteriorated to G3

Patient with good PR until 06/2019

What to do now?

1. Restart CPI

Rash completely resolves after 1 week

63 y/o woman

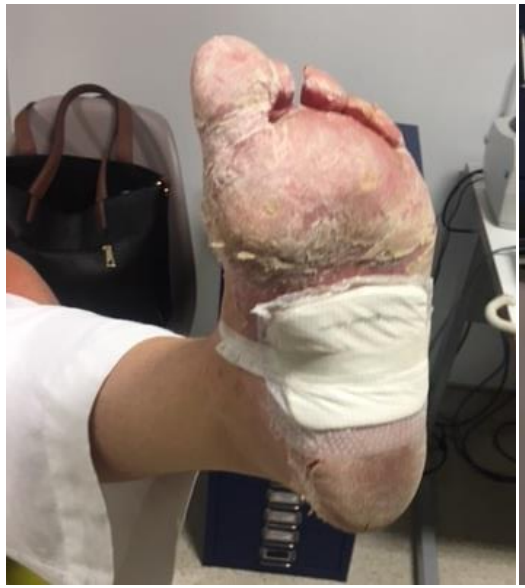
Patient presenting with new rash several weeks after starting on CPI

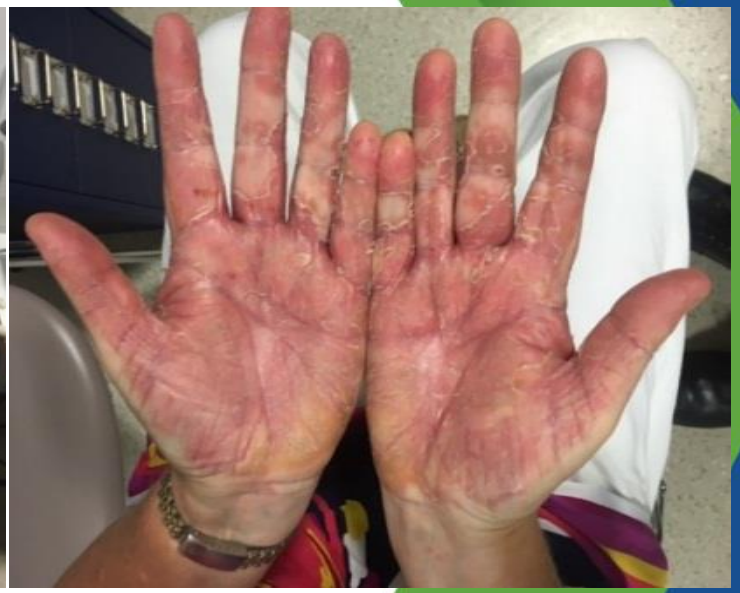
What to do?

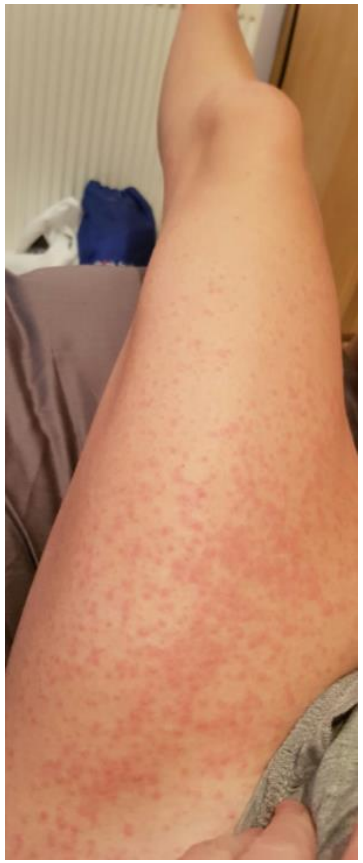
1. **Observe**
2. **Topical steroids**
3. **Oral steroids**

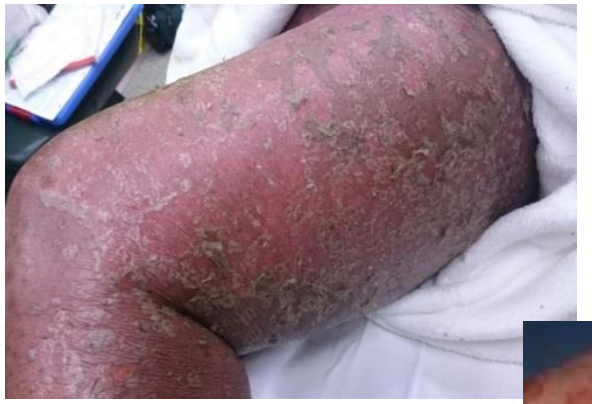
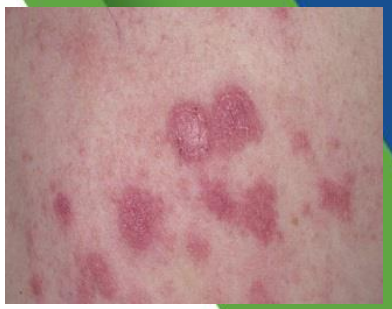
Advice was given to observe

4 weeks later





Key Takeaways

- Immunotherapy has improved pCR and long term outcomes in early stage TNBC and should be considered.
- For metastatic TNBC – using as early as possible has shown improvement in PFS and OS
- Immunotoxicity patterns are different in many cases from standard expected chemotherapy toxicities.
  - Have a low threshold for evaluation as they can escalate quickly.

Society for Immunotherapy of Cancer

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Practical Management Pearls for Immunotherapy for the Treatment of Renal Cell Carcinoma

December 17, 2021, 11 a.m. – 12 p.m. ET

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