ADVANCES IN Cancer IMMUNOTHERAPY™

Immunotherapy of Hematologic Malignancies

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Association of Community Cancer Centers

Society for Immunotherapy of Cancer

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Disclosures

- Research funding from: Celgene, BMS
- I will be discussing non-FDA approved indications during my presentation.

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Patient Selection Criteria for Immune-Based Approaches

- Expression of the desired antigen for CAR-T therapy:
  - e.g. CD19 or BCMA for CAR-T cells
- Disease burden
  - <30% in certain CAR-T trials to minimize the risk of cytokine release syndromes
- Expression of the ligand for checkpoint inhibition
  - e.g. PD-L1 expression for anti-PD-1 therapy
- Presence of co-morbidities:
  - e.g. Presence of active autoimmune diseases which could be worsened

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Lymphomas

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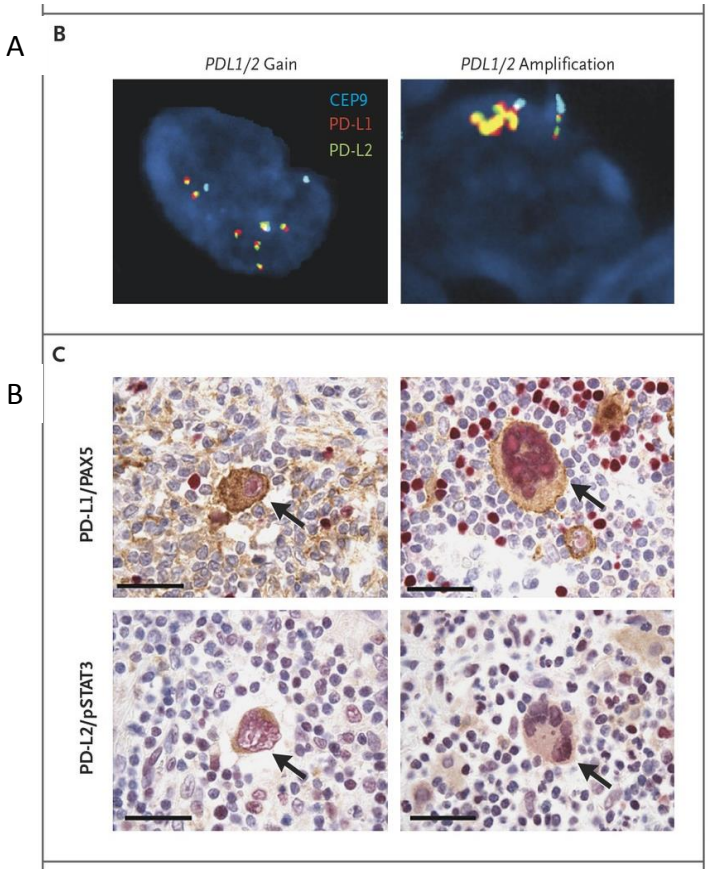
PD-L1 Expression in Hodgkin's Lymphoma

- Reed-Sternberg cells express both PD-L1 and PD-L2
- Expression of ligands increases with advanced disease
- Unclear whether PD-L1/L2 expression correlates with response to treatment



Ansell SM et al. N Engl J Med 2015;372:311-319

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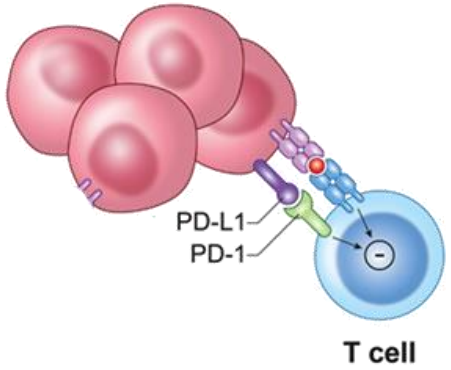

Anti-PD-1 in Hodgkin's Lymphoma

Table 3. Clinical Activity in Nivolumab-Treated Patients.*

Variable	All Patients (N=23)	Failure of Both Stem-Cell Transplantation and Brentuximab (N=15)	No Stem-Cell Transplantation and Failure of Brentuximab (N=3)	No Brentuximab Treatment (N=5)†
Best overall response — no. (%)				
Complete response	4 (17)	1 (7)	0	3 (60)
Partial response	16 (70)	12 (80)	3 (100)	1 (20)
Stable disease	3 (13)	2 (13)	0	1 (20)
Progressive disease	0	0	0	0
Objective response				
No. of patients	20	13	3	4
Percent of patients (95% CI)	87 (66–97)	87 (60–98)	100 (29–100)	80 (28–99)
Progression-free survival at 24 wk — % (95% CI)‡	86 (62–95)	85 (52–96)	NC§	80 (20–97)
Overall survival — wk				
Median	NR	NR	NR	NR
Range at data cutoff¶	21–75	21–75	32–55	30–50

* NC denotes not calculated, and NR not reached.
† In this group, two patients had undergone autologous stem-cell transplantation and three had not.
‡ Point estimates were derived from Kaplan–Meier analyses; 95% confidence intervals were derived from Greenwood's formula.
§ The estimate was not calculated when the percentage of data censoring was above 25%.
¶ Responses were ongoing in 11 patients.

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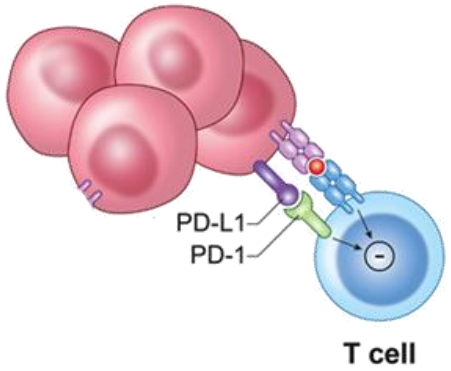

Anti-PD-1 in Hodgkin's Lymphoma

Table 1

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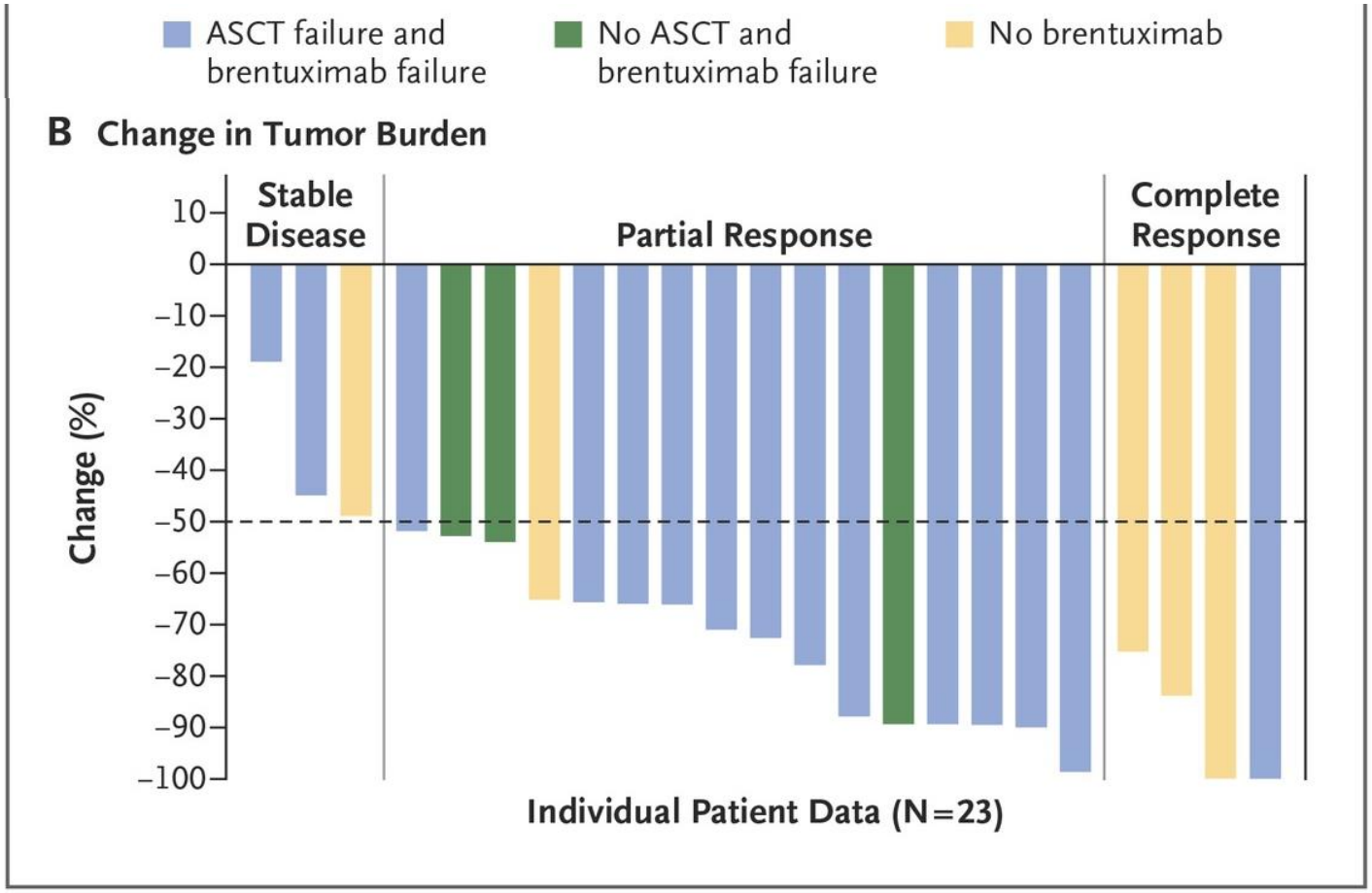

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Nivolumab in R/R B Cell Malignancies: Efficacy

Types	N	ORR, n (%)	CR, n (%)	PR, n (%)	SD, n (%)
B cell lymphoma	29	8 (28)	2 (7)	6 (21)	14 (48)
DLBCL	11	4 (36)	1 (9)	3 (27)	3 (27)
FL	10	4 (40)	1 (10)	3 (30)	6 (60)
T cell lymphoma	23	4 (17)	0	4 (17)	10 (43)
Mycosis fungoides	13	2 (15)	0	2 (15)	9 (69)
PTCL	5	2 (40)	0	2 (40)	0
Multiple myeloma	27	0	0	0	18 (67)
Primary mediastinal B-cell lymphoma	2	0	0	0	2 (100)

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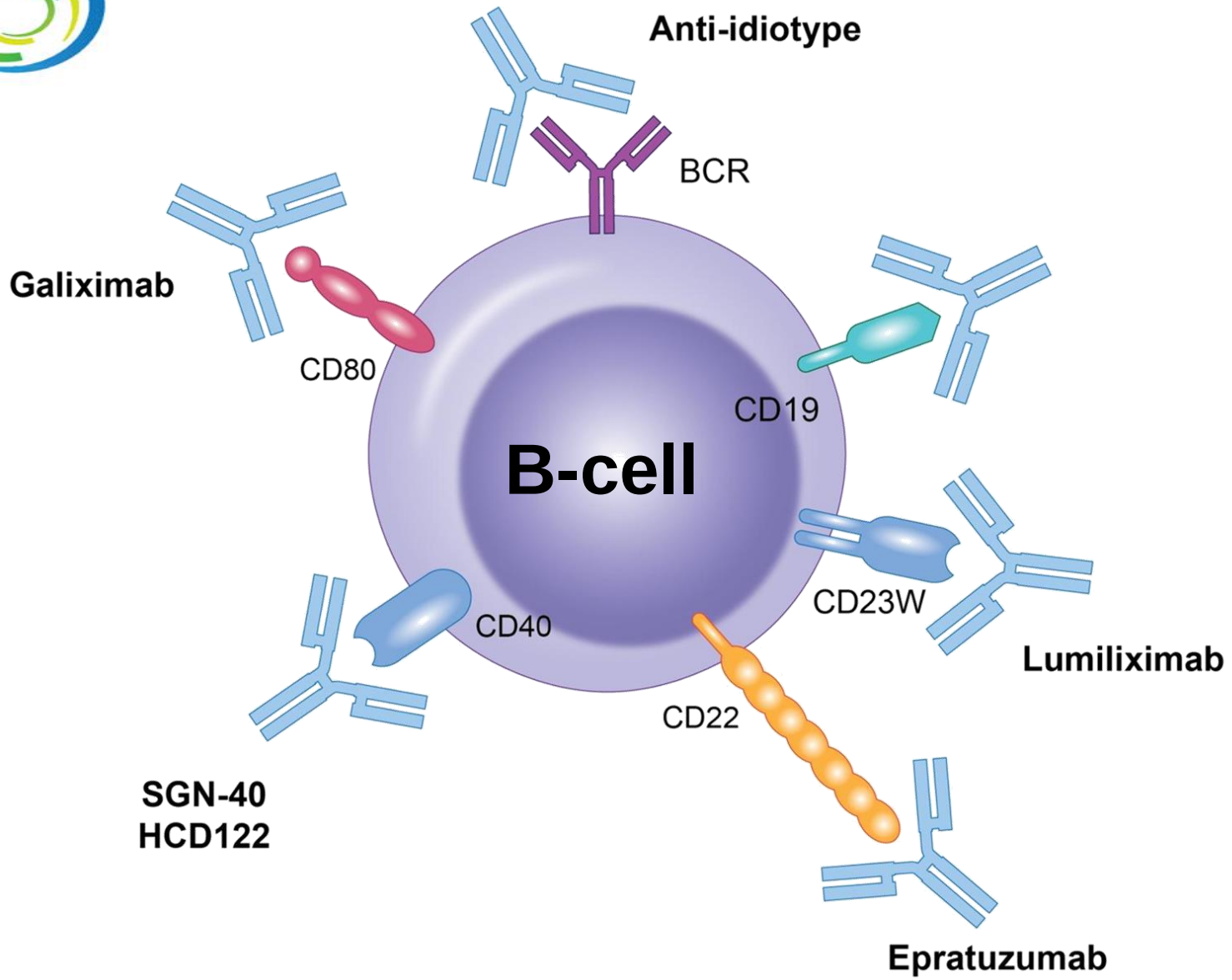
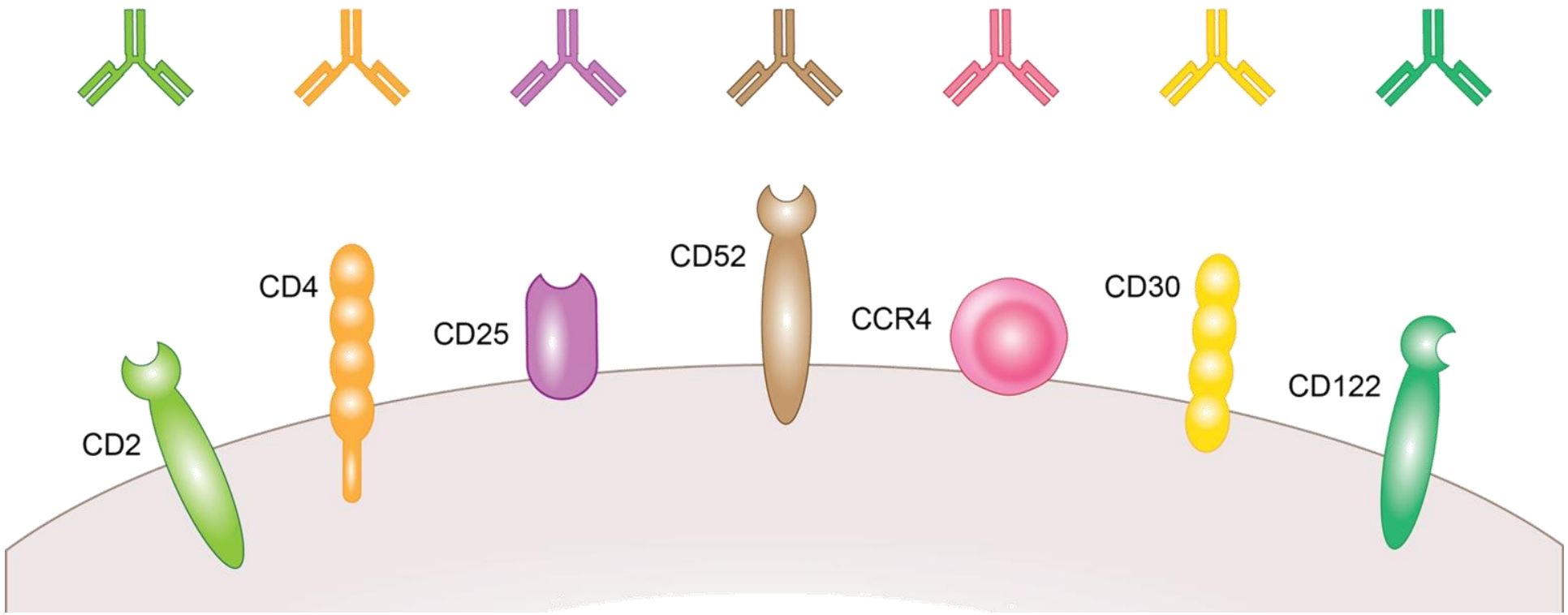

Anti-idiotype
BCR
Galiximab
CD80
CD19
B-cell
CD23W
Lumiliximab
CD40
CD22
SGN-40
HCD122
Epratuzumab

Several monoclonal antibodies targeting T-cell lymphomas



BiTE: Blinatumumab

- Combines the F(ab) of an antibody with an anti-CD3 F(ab)
- Lacks the Cf region
- Requires continuous infusions
- Shown considerable activity in:
    - Follicular NHL
    - DLBCL
    - ALL

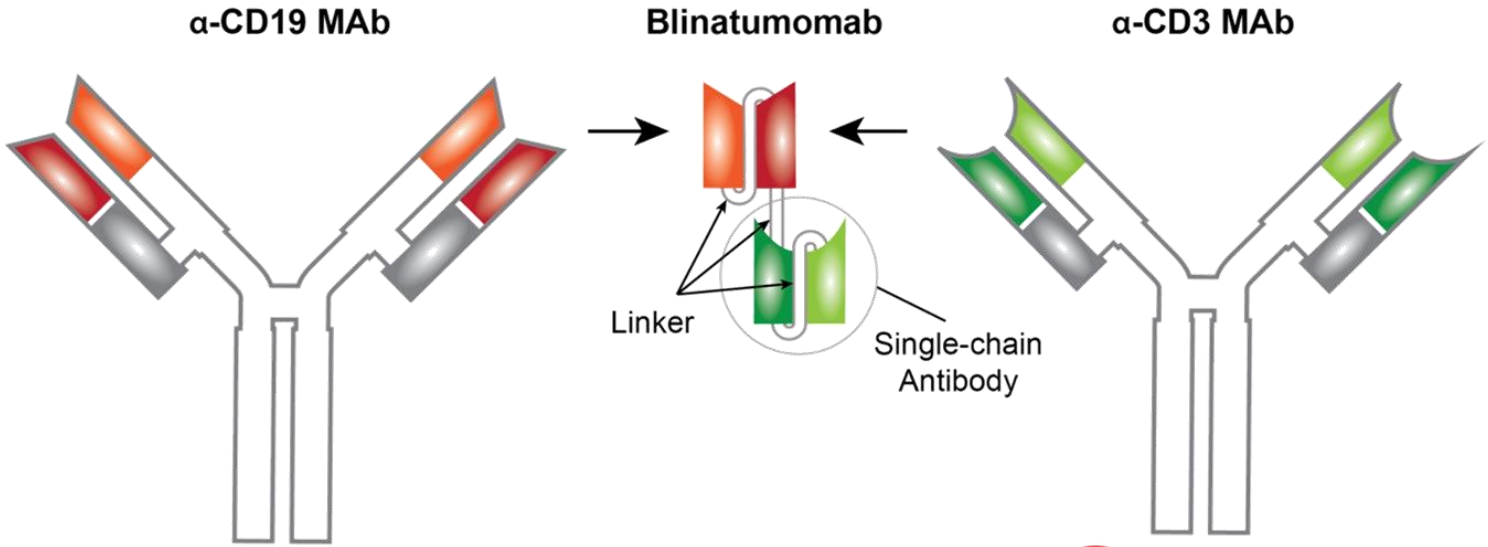


Table 1. Baseline Demographic and Clinical Characteristics

Characteristic	All Patients (n = 76)	Patients in the Extension Phase* (n = 34)
Median (range) age, years	65 (20-80)	62 (20-80)
Sex, No. (%)		
Female	19 (25)	11 (32)
Male	57 (75)	23 (68)
Median (range) time from diagnosis, years	4.0 (1-28)	2.3 (1-28)
Median (range) time from last chemotherapy regimen, months	8.3 (0-100)	6.5 (1-81)
Median (range) number of previous treatment regimens	3 (1-10)	3 (1-8)
Type of prior treatment regimen,† No. (%)		
One or more rituximab treatments	71 (93)	33 (97)
Fludarabine	23 (30)	5 (15)
Autologous HSCT	23 (30)	15 (44)
Histology, No. (%)		
Indolent lymphoma	52 (68)	18 (53)
Follicular lymphoma	28 (37)	10 (29)
Mantle cell lymphoma	24 (32)	8 (24)
Refractory to previous rituximab treatment‡	20 (26)	8 (24)
Diffuse large B-cell lymphoma	14 (18)	13 (38)
Relapsed after previous therapy with CHOP	10 (13)	10 (29)
Relapsed after previous autologous HSCT	9 (12)	9 (26)
Other§	10 (13)	3 (9)

Abbreviations: CHOP, cyclophosphamide, doxorubicin, vincristine, prednisone; HSCT, hematopoietic stem cell transplantation.
*At time of enrollment.
†Individual chemotherapy regimens that were administered during the same time period were considered combination therapies.
‡Stop of last rituximab dose less than 6 months (182 days) before start of next therapy.
§Includes lymphoplasmocytic lymphoma (n = 2), small lymphoplasmocytic lymphoma, immunocytoma, Waldenström macroglobulinemia, marginal zone non-Hodgkin lymphoma, marginal zone B-cell lymphoma, marginal zone lymphoma, chronic lymphocytic leukemia, and small lymphoplasmocytic lymphoma/chronic lymphocytic leukemia (protocol deviations).

Maria-Elisabeth Goebeler; et al. *JCO* **2016,** 34, 1104-1111.

Table 5. Clinical Response

	Dose ($\mu g/m^2$/day)	No. of Patients	No. of Responses						
			CR	CRu	CR/CRu	PR	ORR CR + CRu + PR, n (%)	SD	PD
Response at highest actual dose received*	0.5, 1.5	9	0	0		0	0 (0)	4	5
	5	7†	0	0		0	0 (0)	4	2
	15	15†	1	0		2	3 (20)	7	4
	30	6†	1	0		0	1 (17)	2	2
	60	35†	8	5		11	24 (69)	5	5
	90	4†	1	0		1	2 (50)	1	0
Response at target dose*									
By histology									
FL	60	15			6	6	12 (80)		
MCL	60	7			3	2	5 (71)		
DLBCL‡	60§	11			4	2	6 (55)		
Other	60	2			0	1	1 (50)		
By early relapse status‖									
Early relapse	60	19			5	5	10 (53)		
No early relapse	60	16			8	6	14 (88)		

Abbreviations: CR, complete response; CRu, unconfirmed complete response; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; MCL, mantle cell lymphoma; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease.

*During the first treatment period only (not including consolidation treatment).

†One patient did not have a response assessment. Five patients had no response data available (MCL, n = 4; FL, n = 1) but were included in the statistical response analysis calculations.

‡Three patients with DLBCL did not receive the target dose (study termination before dose step to target dose, n = 2; one patient was treated in the 30 $\mu g/m^2$/day dose group).

§One patient received 30 $\mu g/m^2$/day.

‖Early relapse: end of last chemotherapy less than 12 months before blinatumomab treatment start. No early relapse: end of last chemotherapy 12 months or more before blinatumomab treatment start.

Maria-Elisabeth Goebeler; et al *JCO* **2016,** 34, 1104-1111.

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Phase 2 study of the bispecific T-cell engager (BiTE) antibody blinatumomab in relapsed/refractory diffuse large B-cell lymphoma

Andreas Viardot, Marie-Elisabeth Goebeler, Georg Hess, Svenja Neumann, Michael Pfreundschuh, Nicole Adrian, Florian Zettl, Martin Libicher, Cyrus Sayehli, Julia Stieglmaier, Alicia Zhang, Dirk Nagorsen, and Ralf C. Bargou

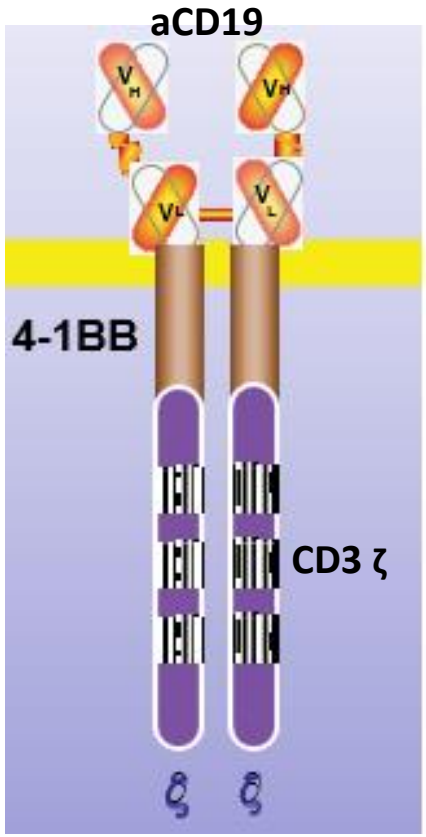
Blood 2016 127:1410-1416; doi: https://doi-org.ezp-prod1.hul.harvard.edu/10.1182/blood-2015-06-651380

Table 4

Best tumor response in cycle 1 per independent radiologic assessment

Patient response rate	Cohorts I + III	Cohort II	Total
Evaluable patients, n*	20	1	21
Overall response rate, n (%)†	8 (40.0)	1 (100.0)	9 (42.9)
Best overall response, n (%)			
CR	4 (20.0)	0 (0.0)	4 (19.0)
PR	4 (20.0)	1 (100.0)	5 (23.8)
Stable disease	2 (10.0)	0 (0.0)	2 (9.5)
Progressive disease	10 (50.0)	0 (0.0)	10 (47.6)
All patients, n	23	2	25
Overall response rate, n (%)†	8 (34.8)	1 (50.0)	9 (36.0)
Best overall response, n (%)			
CR	4 (17.4)	0 (0.0)	4 (16.0)
PR	4 (17.4)	1 (50.0)	5 (20.0)
Stable disease	3 (13.0)	0 (0.0)	3 (12.0)
Progressive disease	10 (43.5)	0 (0.0)	10 (40.0)
No response assessment	2 (8.7)	1 (50.0)	3 (12.0)

Chimeric Antigen Receptor for CD19 (CTL019)



Extracellular domain

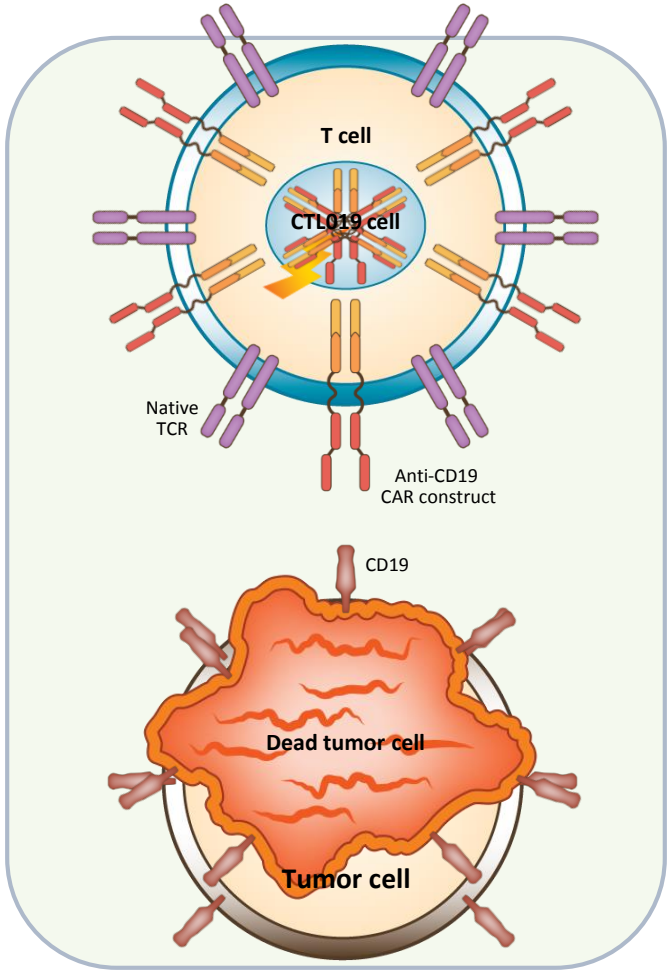
- FMC63 **mouse** hybridoma derivative

Intracellular domain

- Fusion protein

Redirecting the Specificity of T cells

- Gene transfer technology stably expresses CARs on T cells[1,2]
- CAR T cell therapy takes advantage of the cytotoxic potential of T cells, killing tumor cells in an *antigen-dependent* manner[1,3]
- Persistent CAR T cells consist of both effector (cytotoxic) and central memory T cells[3]
- **T cells are *non-cross resistant* to chemotherapy**



1. Milone MC, et al. *Mol Ther.* 2009;17:1453-1464.
2. Hollyman D, et al. *J Immunother.* 2009;32:169-180.
3. Kalos M, et al. *Sci Transl Med.* 2011;3:95ra73.

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CAR T-cell therapies in DLBCL

Efficacy and safety

	CTL019[1]	KTE-C19[2,3]		JCAR017[4,5]
Disease state	r/r DLBCL	r/r DLBCL	r/r TFL/PMBCL	r/r DLBCL, NOS, tDLBCL, FL3B
Pts treated, n	85	77	24	28
Follow-up, median	NR	8.7 mo		NR
Efficacy				
ORR (best response)	59%	82%	83%	80%[a]
CR (best response)	**43%**	**54%**	**71%**	**60%[a]**
CR (3 months)	37%	NR	NR	45%
CR (6 months)	NR	31%	50%	NR
Safety				
CRS	31% grade 1/2; 26% grade 3/4	13% grade ≥3		36% grade 1/2; 0% grade 3/4
Neurotoxicity	13% grade 3/4	28% grade ≥3		4% grade 1/2; 14% grade 3/4

[a]20 pts with DLBCL were evaluated for efficacy.

CR, complete response; CRS, cytokine release syndrome; NR, not reported; ORR, overall response rate.

1. Schuster, SJ, et al. ICML 2017 [abstract 007]. 2. Locke FL, et al. AACR 2017 [abstract CT019]; 3. Locke FL, et al. ASCO 2017 [abstract 7512]; 4. Abramson JS, et al. *Blood*. 2016;128(22) [abstract 4192]; 5. Abramson JS, et al. ASCO 2017 [abstract 7513].

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CAR T-cell therapies in DLBCL

UPENN Single Institution Study

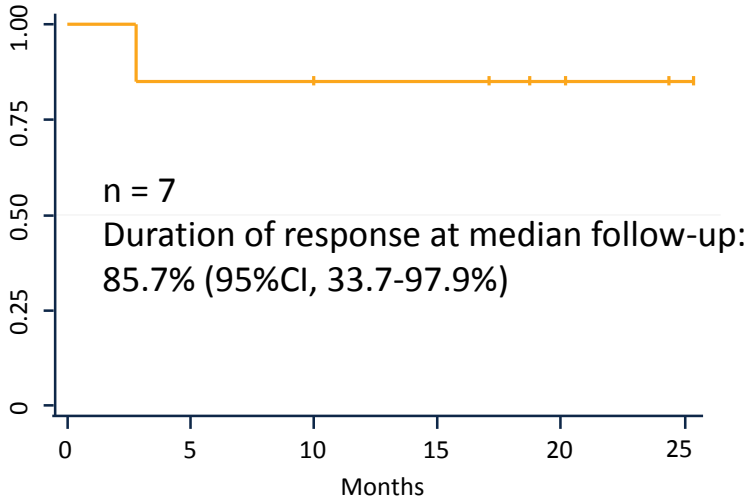
- Results from a single-center, phase 2 study at the University of Pennsylvania showed durable remissions with a single infusion of CTL019 in r/r DLBCL (Cohort A)[1,2]
  - No patient in CR at 6 months has relapsed (median follow-up, 23.3 months)

Response Rates (N = 15)

	Month 3	Month 6
ORR	7 (47%)	7 (47%)
CR	3 (20%)	6 (40%)
PR	4 (27%)	1 (7%)

CR, complete response; DLBCL, diffuse large B-cell lymphoma; ORR, overall response rate; PR, partial response.

Duration of Response (n = 7; CR + PR)



1. Schuster SJ, et al. *Blood*. 2015;126(23):[abstract 183].
2. Schuster SJ, et al. *Blood*. 2016;128(22):[abstract 3026].

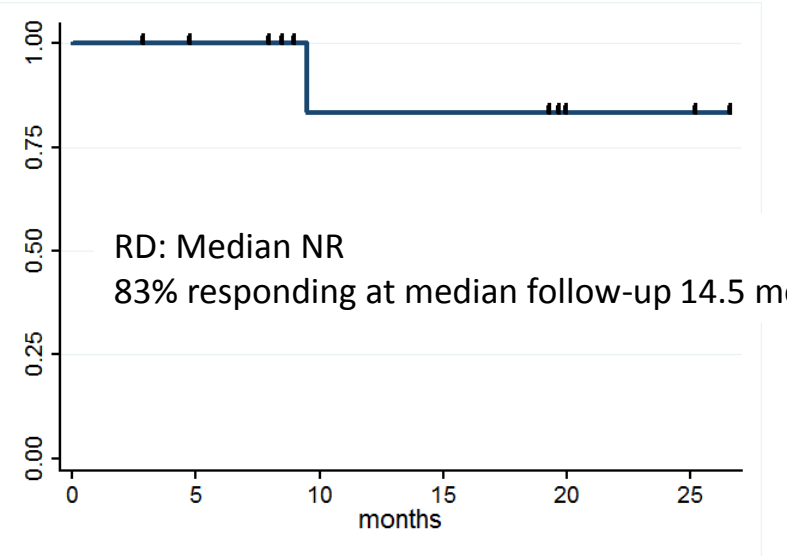
CAR T-cell therapies in FL

UPENN Single Institution Study

FL: ORR at 3 mo. 79% (N = 14)	FL: Best Response Rate 79% (N = 14)
- CR: 7 (50%) - PR: 4 - PD: 3	- CR: 10 (71%) - PR: 1 - PD: 3

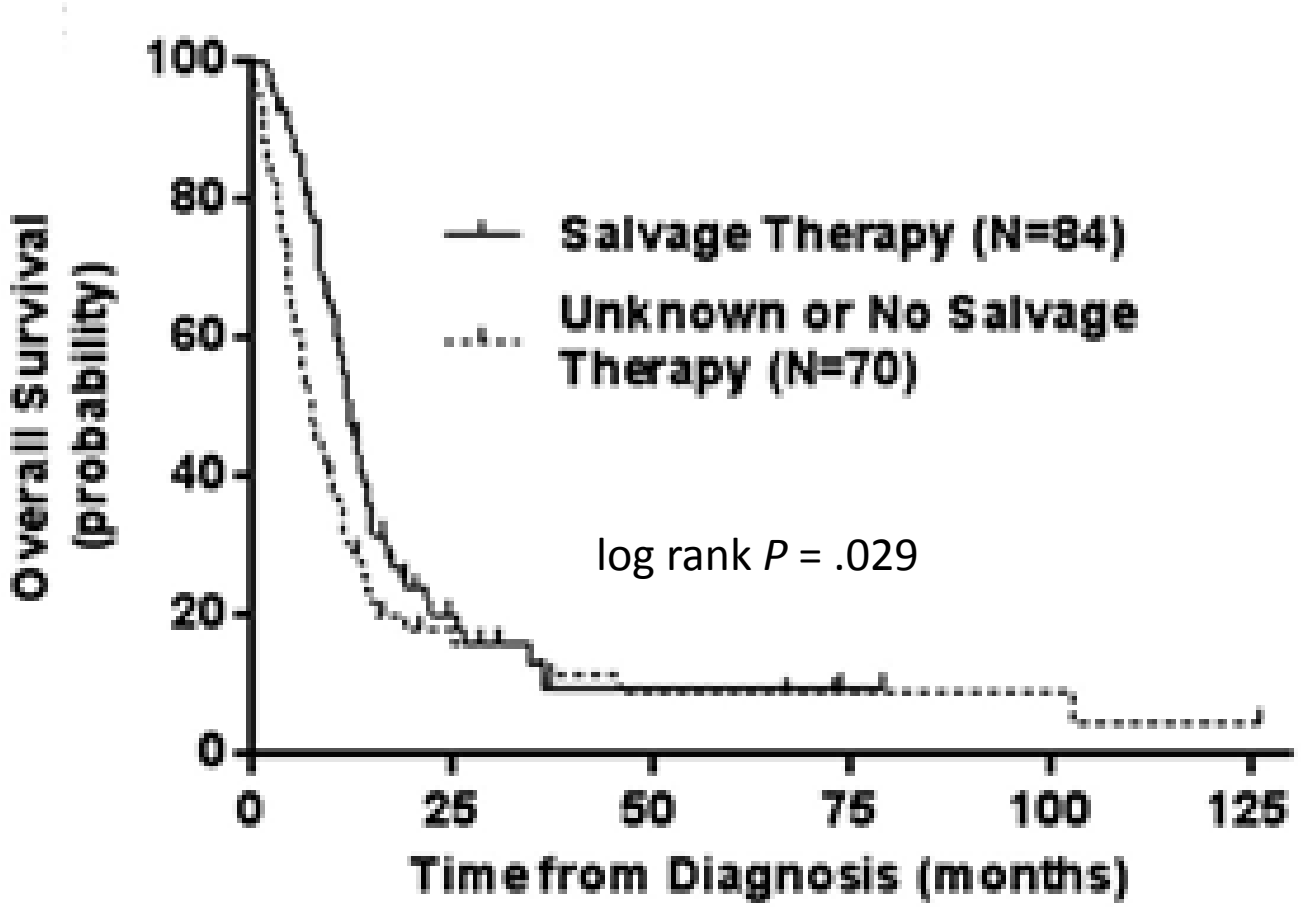
- 3 patients with PRs by anatomic criteria at 3 months converted to CRs by 6 months
- 1 patient with PR at 3 months who remained in PR at 6 and 9 months had PD

Duration of Response
(n = 11; CR + PR)



Chong EA, et al. *Blood*. 2016;128:abstract1100.

Survival for relapsed/refractory double-hit lymphoma: salvage therapy vs palliative care



Petrich AM, et al. *Blood*. 2014;124:2354-2361.

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Leukemia

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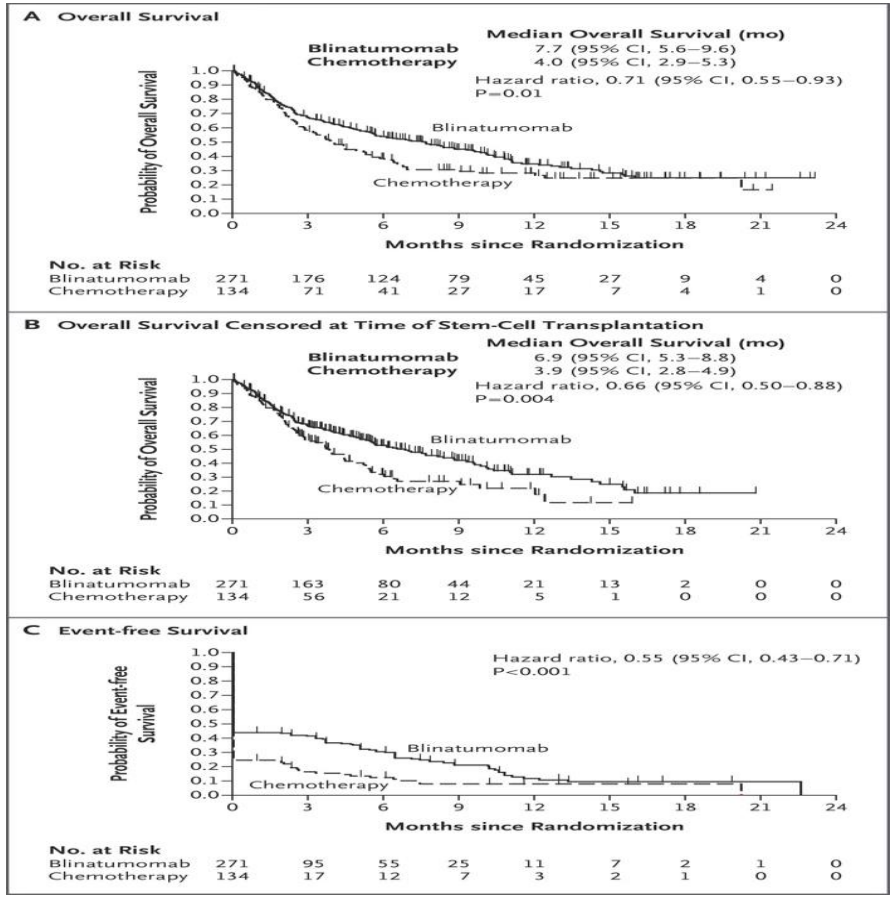
ORIGINAL ARTICLE

Blinatumomab versus Chemotherapy for Advanced Acute Lymphoblastic Leukemia

Hagop Kantarjian, M.D., Anthony Stein, M.D., Nicola Gökbuget, M.D., Adele K. Fielding, M.B., B.S., Ph.D., Andre C. Schuh, M.D., Josep-Maria Ribera, M.D., Ph.D., Andrew Wei, M.B., B.S., Ph.D., Hervé Dombret, M.D., Robin Foà, M.D., Renato Bassan, M.D., Önder Arslan, M.D., Miguel A. Sanz, M.D., Ph.D., Julie Bergeron, M.D., Fatih Demirkan, M.D., Ewa Lech-Maranda, M.D., Ph.D., Alessandro Rambaldi, M.D., Xavier Thomas, M.D., Ph.D., Heinz-August Horst, M.D., Ph.D., Monika Brüggemann, M.D., Wolfram Klapper, M.D., Ph.D., Brent L. Wood, M.D., Ph.D., Alex Fleishman, M.S., Dirk Nagorsen, M.D., Ph.D., Christopher Holland, M.S., Zachary Zimmerman, M.D., Ph.D., and Max S. Topp, M.D.

N Engl J Med 2017; 376:836-847 | March 2, 2017 | DOI: 10.1056/NEJMoa1609783



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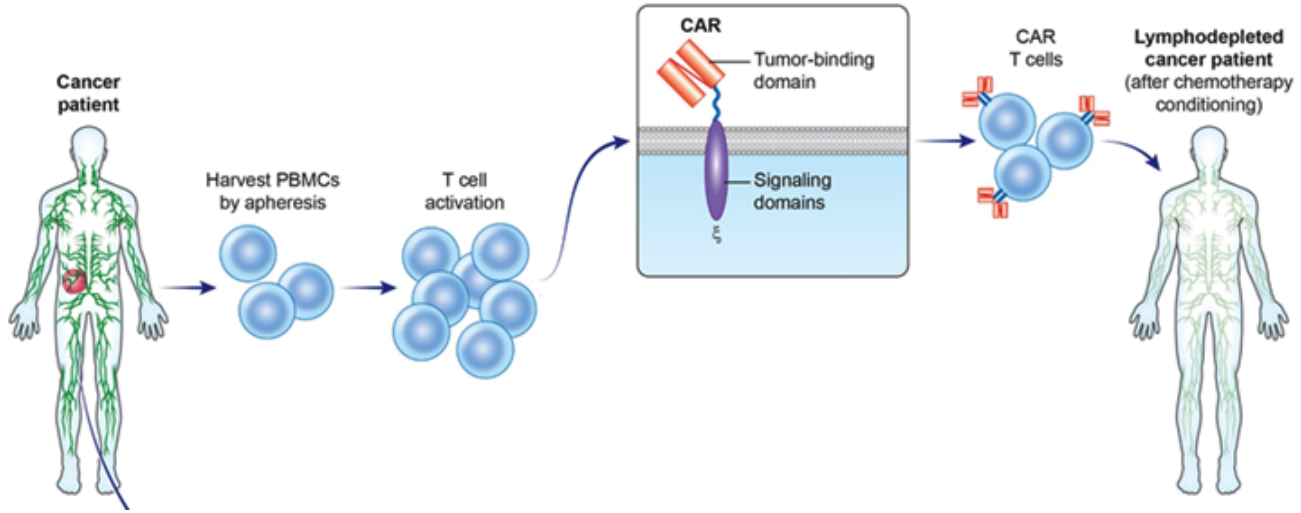
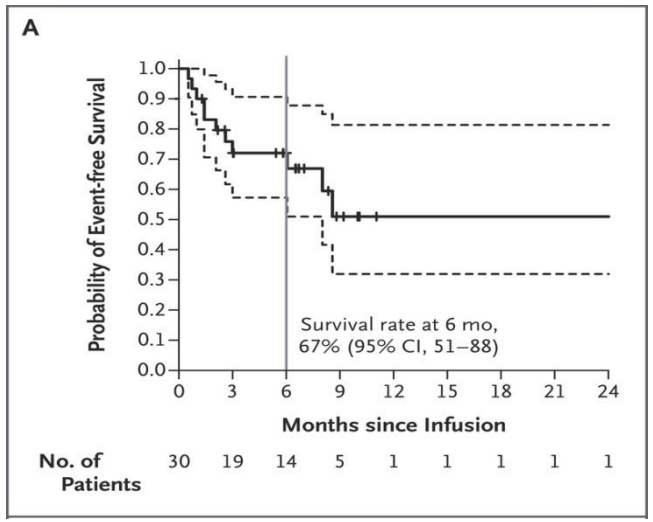
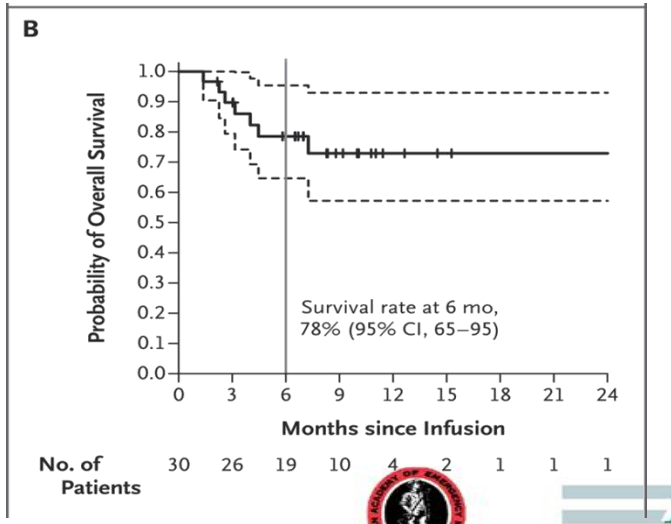
CD-19 CAR-T in ALL

Probability of Event-Free and Overall Survival at Six Months.







Maude SL et al. N Engl J Med 2014;371:1507-1517.

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Antigen-specific Approaches in ALL

Technology:	CART	ADC	BiTE
Example	CART-19	Inotuzumab (anti-CD22 + toxin)	Blinatumumab (anti-CD3/CD19)
Dosing	One infusion	Every 3 weeks	Continuous 28 days
Complete Response	90%	19%	66%
Survival	78% 6 mos OS	5-6 months median	9 mos median
Major toxicity	Cytokine release	Hepatotoxicity	Cytokine release
Antigen loss relapse?	Yes	No	Yes
Challenges	Complex manufacturing, individualized	Lower response rates	Burdensome infusion

Gill Immunol Rev Dec 2014

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Myeloma

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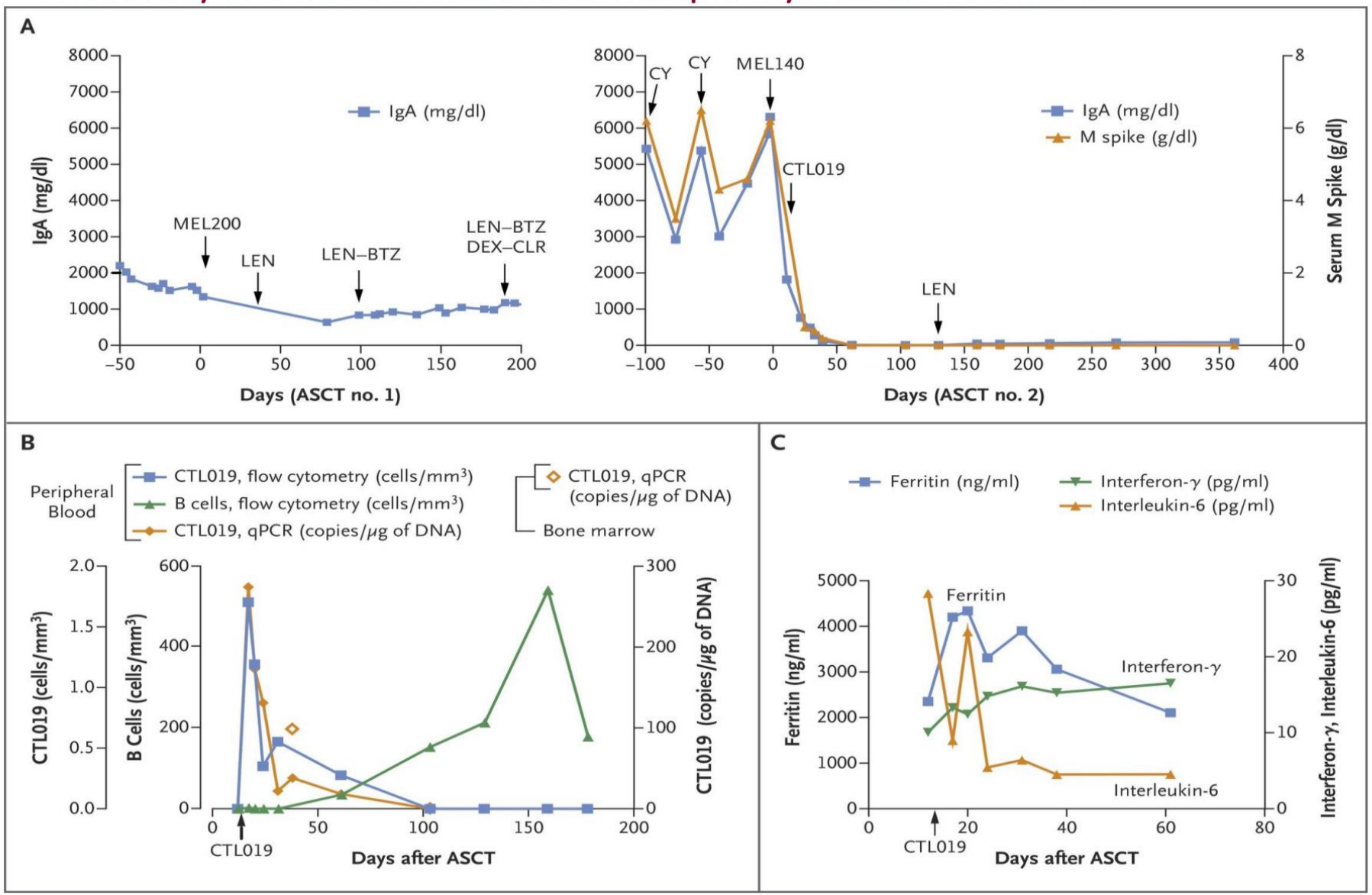
Pilot Study of CTL019 in Advanced Multiple Myeloma: Pt 02413-01



Garfall et al, NEJM September 10 2015

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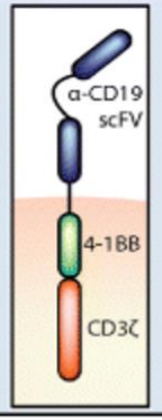
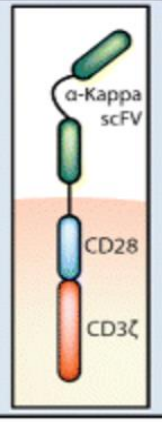
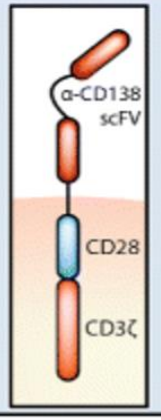
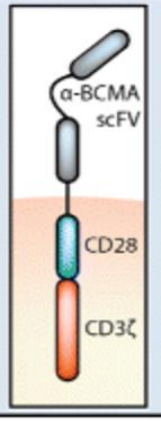
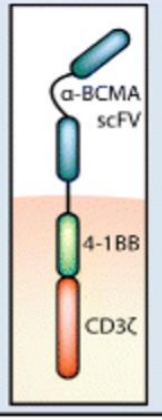
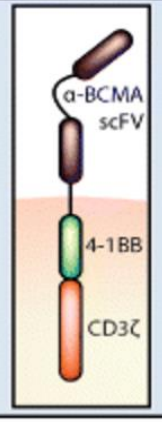
CAR T Cells in Development for Myeloma

	α-CD19-BBz	α-Kappa-28z	α-CD138-28z	α-BCMA-28z	α-BCMA-BBz	α-BCMA-BBz
						
Institution	Penn	Baylor	Chinese PLA General Hospital	NCI	Penn	bluebird bio
scFV Clone	FMC63	CRL-1758	NK-92	11D5-3	ND	bb2121
scFV Origin	Murine	Murine	Murine	Murine	Human	Humanized
Gene Transfer System	Lentivirus	Retrovirus	Lentivirus	Retrovirus	Lentivirus	Lentivirus
Intracellular Domain	4-1BB ICD-CD3zeta	CD28 ICD-CD3zeta	CD28 ICD-CD3zeta	CD28 ICD-CD3zeta	4-1BB ICD-CD3zeta	4-1BB ICD-CD3zeta
Patients Treated	11	8	5	12	6	9
Dose(s)	1-5e7 CARTs/pt	0.2-2e8 CARTs/m2	0.44-1.51e7 CARTs/kg	0.3-9e6 CARTs/kg	1e7-5e8 CARTs/pt	5-80e7 CARTs/pt
Best Response (number of patients)	CR (1), VGRP (6), PR (2), PD (2)	SD (5), NR (3)	SD (4), PD (1)	Stringent CR (1), VGPR (2), PR (1), SD (8)	Stringent CR (1), VGPR (1), SD (1), MR (2), PD (1)	Stringent CR (2), VGPR (1), PR (4), SD (1), PD (1)
Reference(s)	25··	27··	26	28	29	ASH 2016 Abstract

Maria Ormhøj Current Hematologic Malignancy Reports April 2017, Volume 12 (2) pp 119–125

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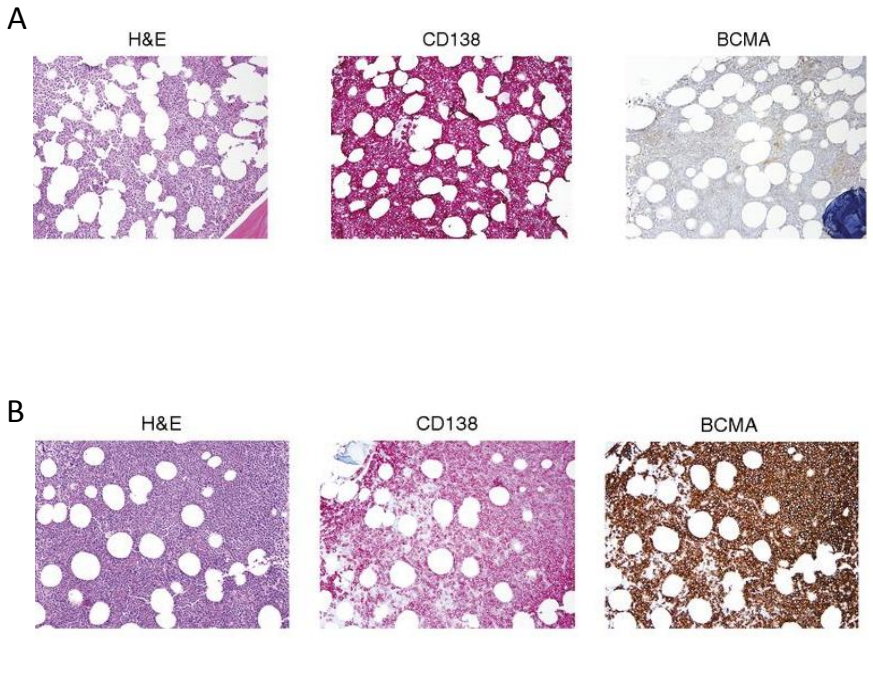
Case Study #2

Two patients with multiply relapsed myeloma considering participation in a BCMA CAR-T cell trial.

Enrollment BM biopsy shows the following staining



Syed Abbas Ali et al. Blood 2016;128:1688-1700

Case Study #2

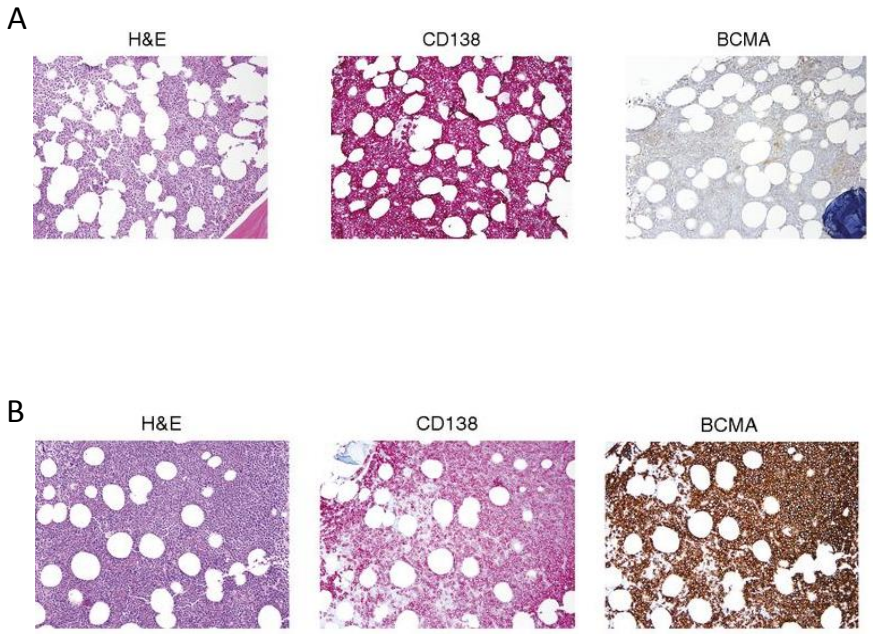
Which of the following statements is true?

A.Pt A more likely to respond to BCMA CAR-T cell therapy

B.Pt B more likely to suffer from cytokine release syndrome (CRS) following BCMA CAR-T cell therapy

C.CRS is independent of disease burden

D.CRS is only seen in ALL



Syed Abbas Ali et al. Blood 2016;128:1688-1700

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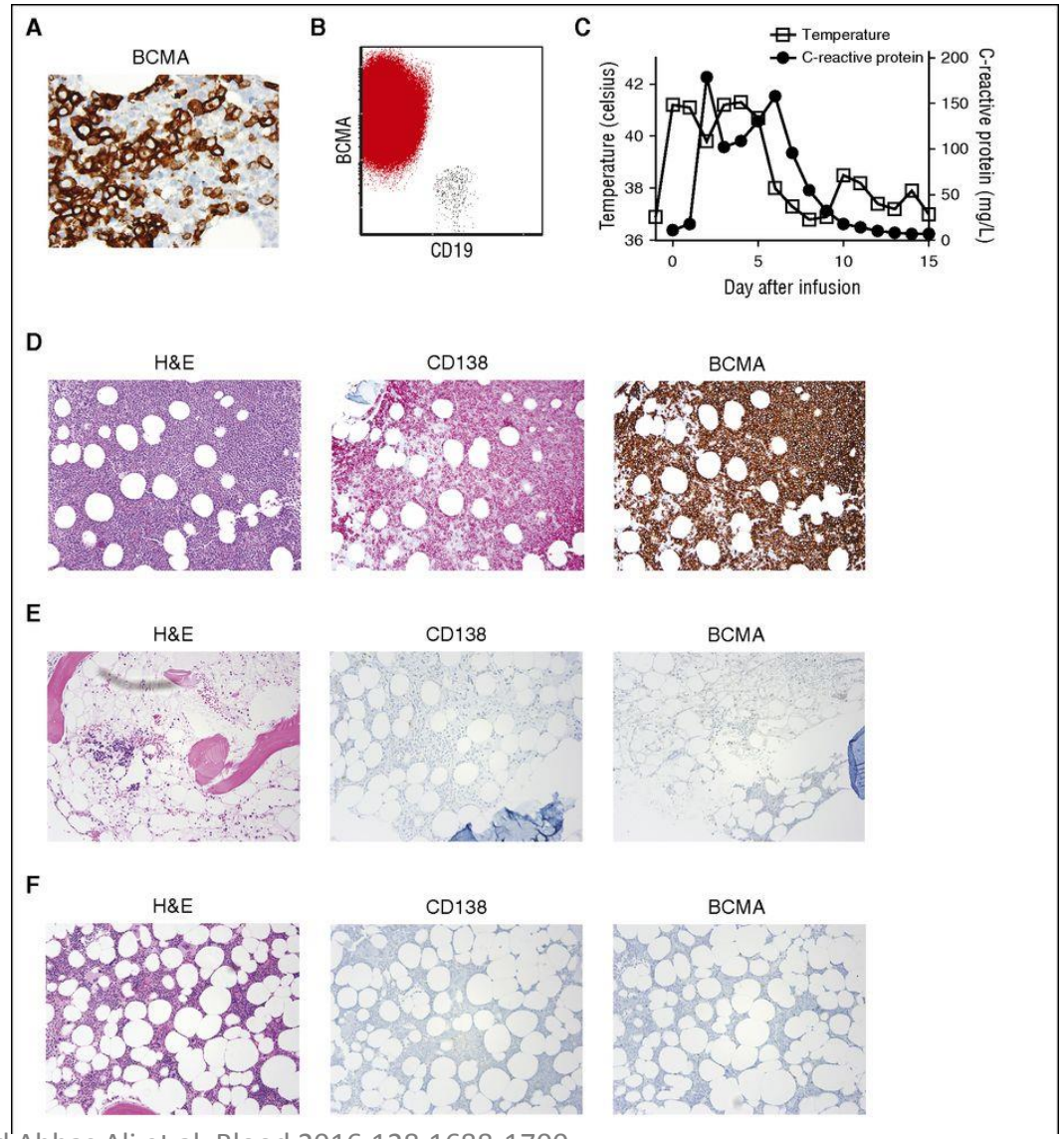
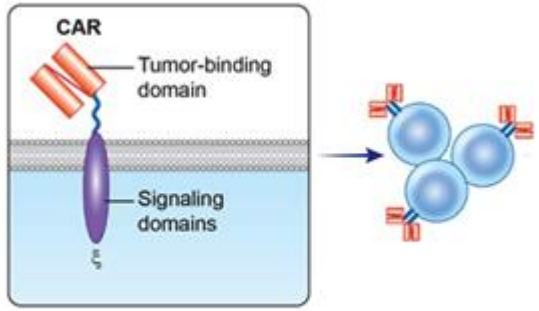
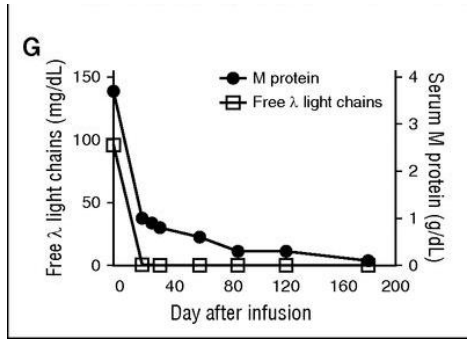
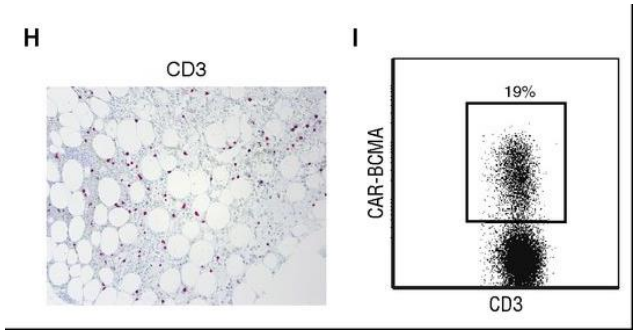
Efficacy of BCMA CAR-T in Myeloma









Syed Abbas Ali et al. Blood 2016;128:1688-1700

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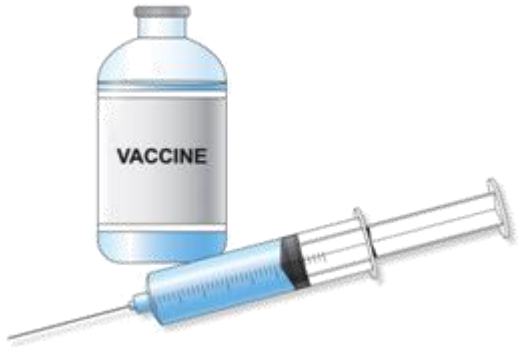
Types of Vaccines Used in Myeloma

- Non-Antigen Specific
  - Attenuated measles
  - Whole cell - GM-CSF
  - Dendritic – tumor fusions
- Antigen Specific
  - Idiotype: RNA, DNA, protein
  - Pulsed dendritic cells
  - Tumor-specific peptides



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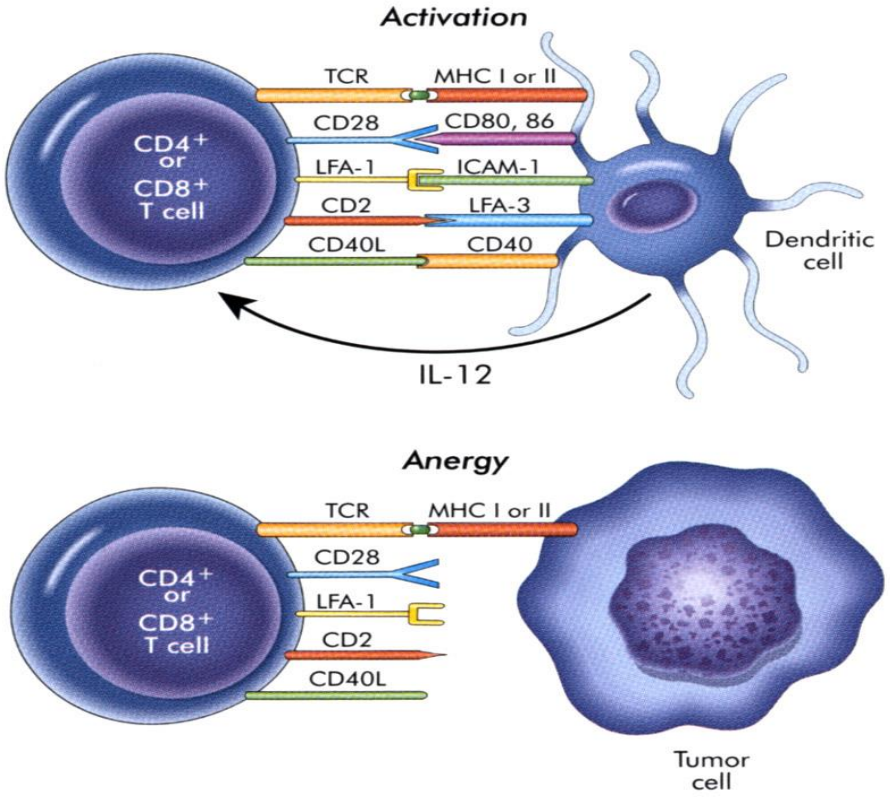
Dendritic Cells as Platform for Cancer Vaccination



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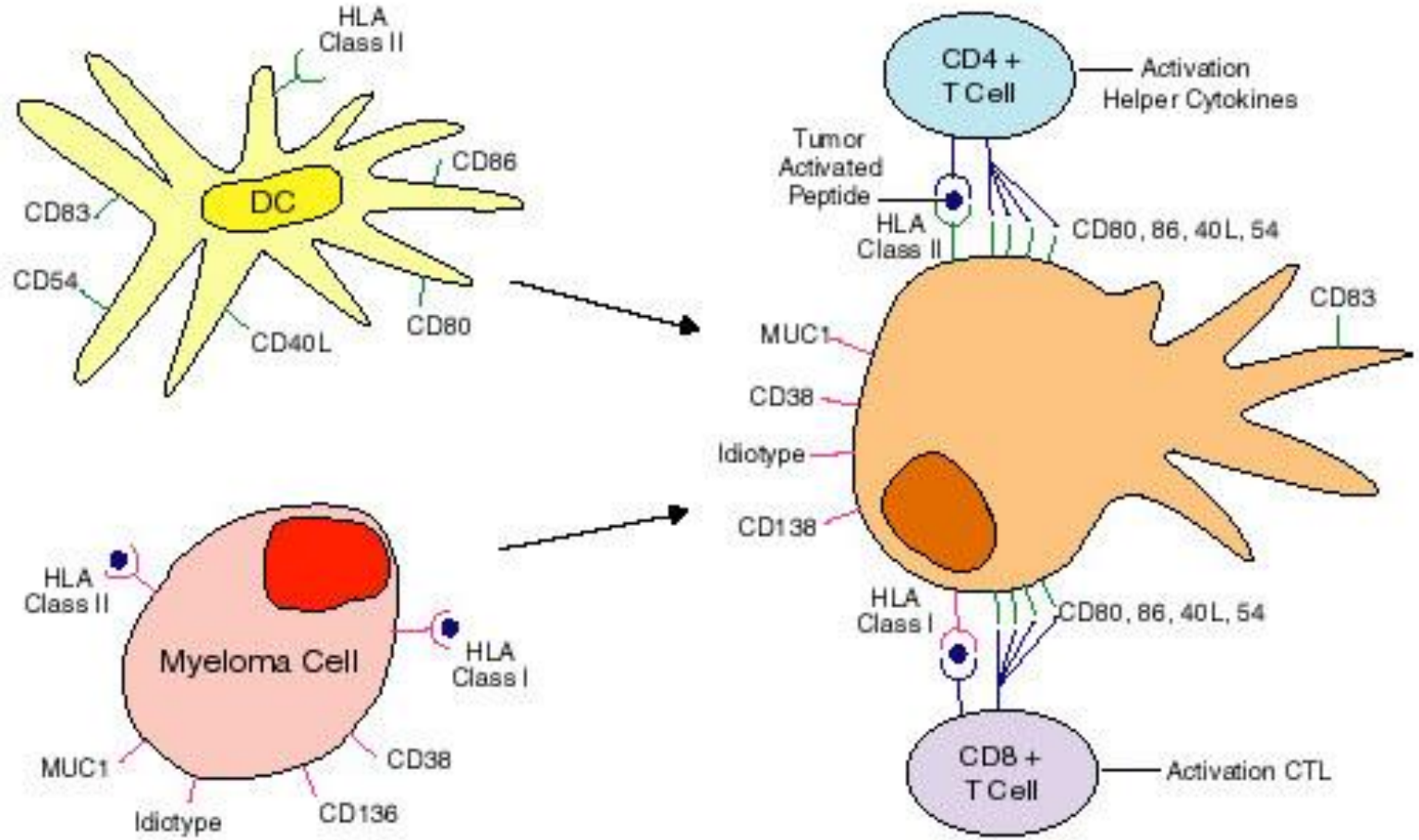
DC/TUMOR FUSION VACCINE



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Vaccination with DC/MM Fusions: Phase 1 Trial

- 17 patients have completed vaccination
- Mean age 57 years old
- Mean BM Plasma Cell Involvement: 35%
- Median number of prior treatment regimens: 4
- 14 patients with prior autologous transplant
- Vaccine Dose:
  - 3 patients: $1x10^6$
  - 4 patients: $2x10^6$
  - 9 patients: $4x10^6$

10 fold expansion of myeloma reactive T cells

Disease stabilization seen in 66% of patients

Rosenblatt et al Blood. 2011 Jan 13;117(2):393-402

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Vaccination in Conjunction with Stem Cell Transplant

- Autologous transplant for myeloma offers a unique opportunity to explore the role of cancer vaccines
  - Patients achieve minimal disease state but transplant is not curative
  - Transplant mediated cytoreduction minimizes immunosuppressive effects of myeloma

- Enhanced response to vaccination post-transplant in animal models
  - Transplant mediated lymphodepletion transiently breaks tolerance due to T-reg suppression
  - Capacity to respond to DC vaccination early post-transplant (Chung et al Canc Immunol Res 2015)

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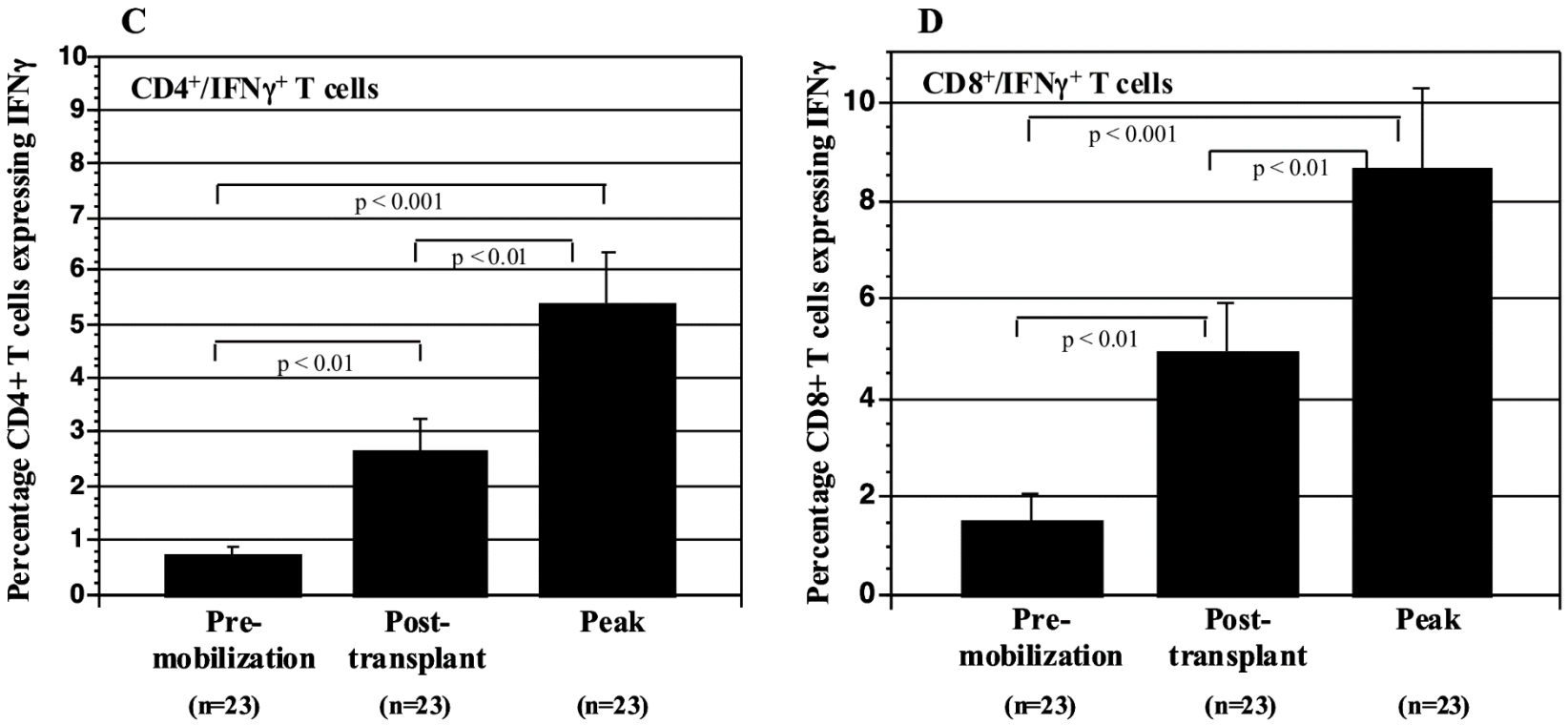
Mean percentage of tumor reactive lymphocytes



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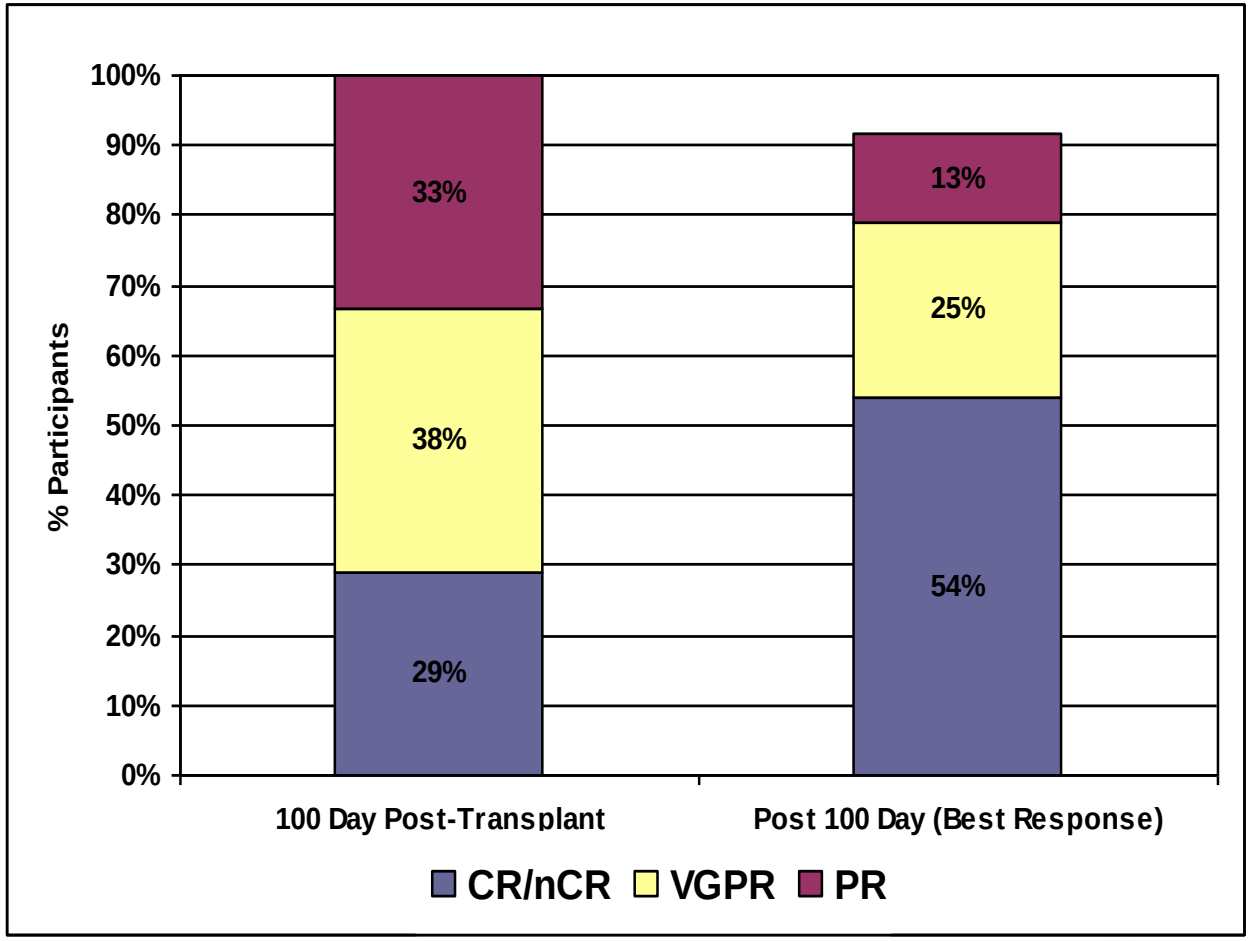
Clinical Response



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BMT CTN Protocol 1401

Phase II Multicenter Trial of Single Autologous Hematopoietic Cell Transplant Followed by Lenalidomide Maintenance for Multiple Myeloma with or without Vaccination with Dendritic Cell (DC)/Myeloma Fusions

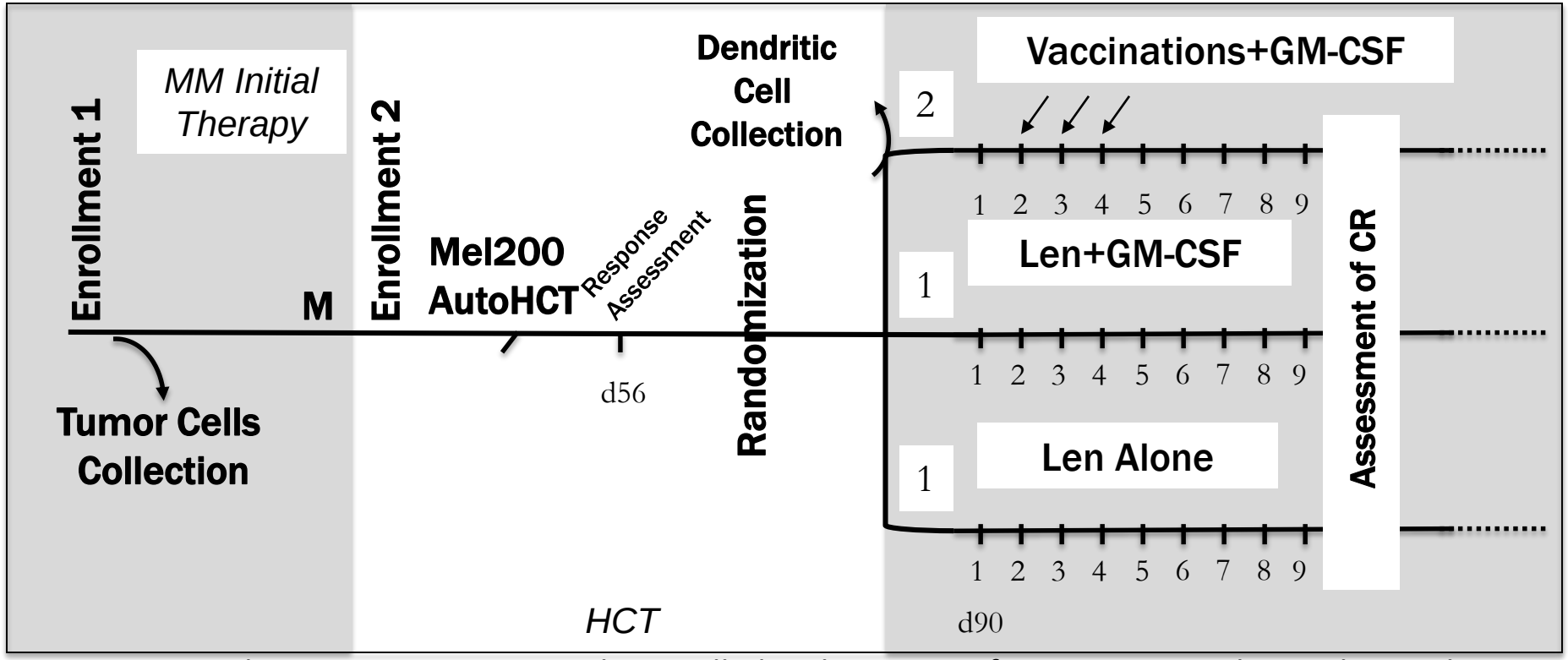
(MY T VAX)

David Avigan, Nina Shah, David Chung

Marcelo Pasquini

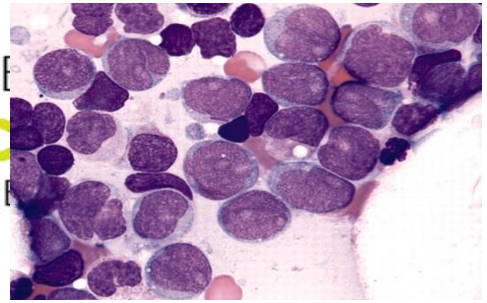
BLOOD AND MARROW TRANSPLANT CLINICAL TRIALS NETWORK

Study Schema



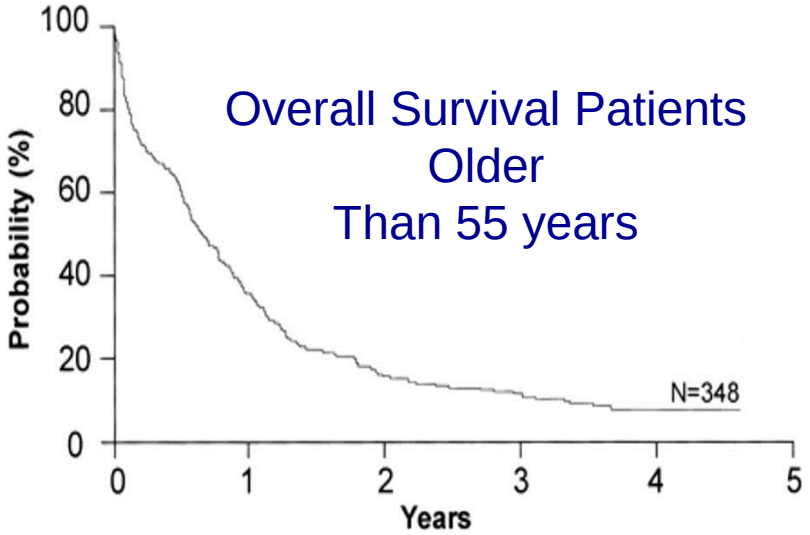
- Accrual targets 188 patients to be enrolled with a target of 132 patients to be randomized
- Assuming about 30% of patients are unable to proceed with post-transplant immunotherapy.
  - Arm A: Maintenance lenalidomide + vaccine + GM-CSF (n=66)
  - Arm B: Maintenance lenalidomode + GM CSF (n=33)
  - Arm C: Maintenance lenalidomide alone (n=33)

  - Patients will be stratified according to disease status at time of randomization between
  - CR and sCR and VGPR/PR/Stable disease.

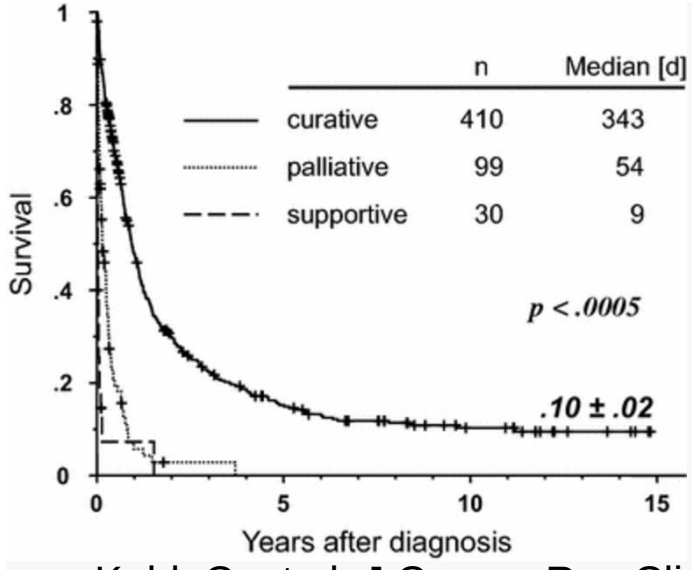


Acute Myeloid Leukemia

- >50% of patients achieve remission but chemotherapy is not curative for most patients
- Outcomes are poor for patients over age 60



Forman, S. J. Hematology 2009:406-413



Kahl, C. et al. J Cancer Res Clin Oncol (2016)142: 305.

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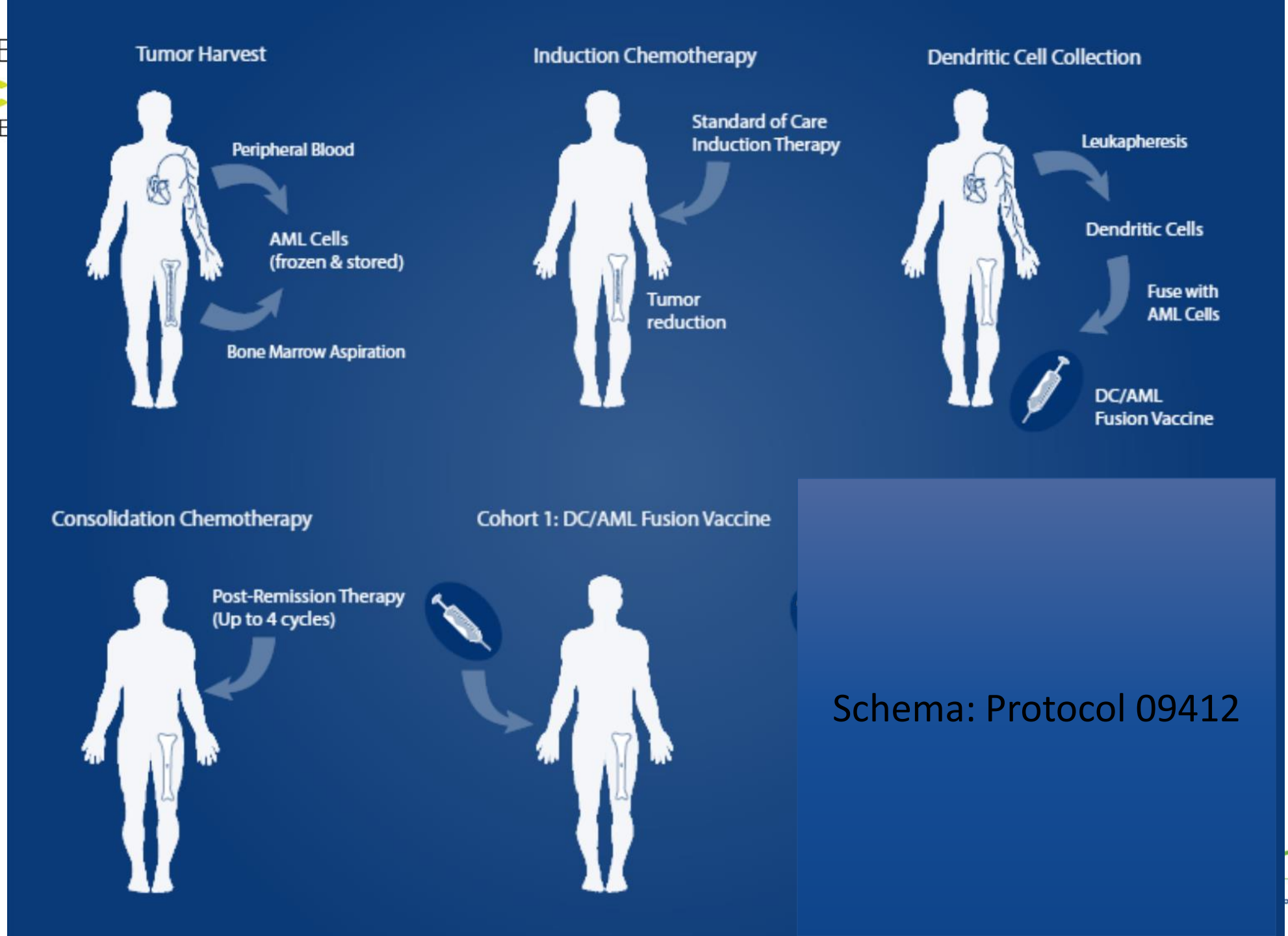

Schema: Protocol 09412

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Characteristics of 19 patients who completed vaccine generation

- Median age was **63 years**
- 11 patients had **intermediate or high risk** disease
- 2 patients completed vaccine generation, but did not receive any vaccination:

- relapsed AML (n=1)
- ongoing chemotherapy toxicity (n=1).

- **17 patients initiated vaccination**:

-16 patients received at least 2 vaccines
- 1 patient relapsed after 1 dose of vaccine

- Median time from completing chemotherapy to initiating vaccination was 56 days (range 38-118 days)

Sci Transl Med. 2016 Dec 7;8(368):368ra171.

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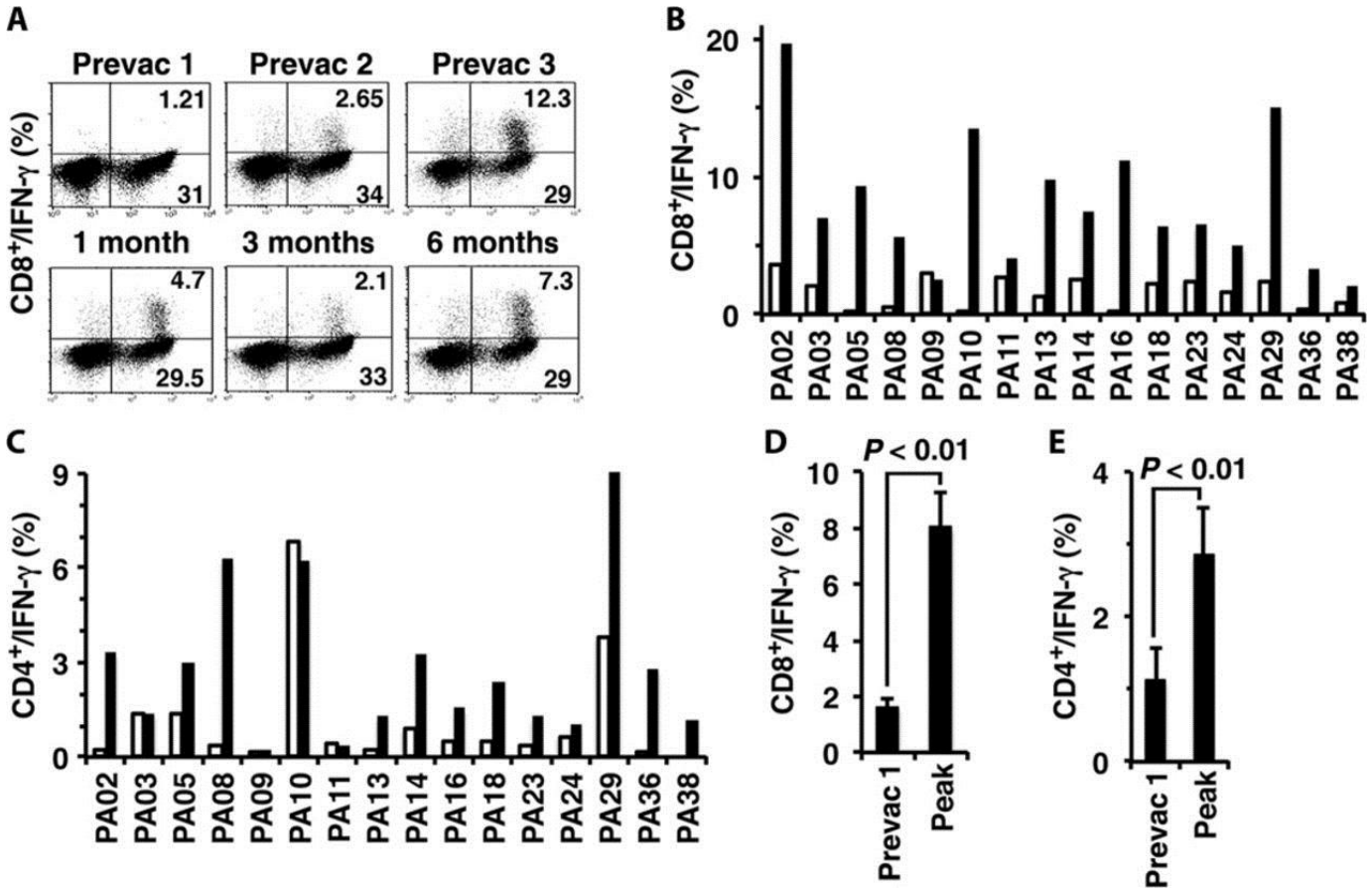
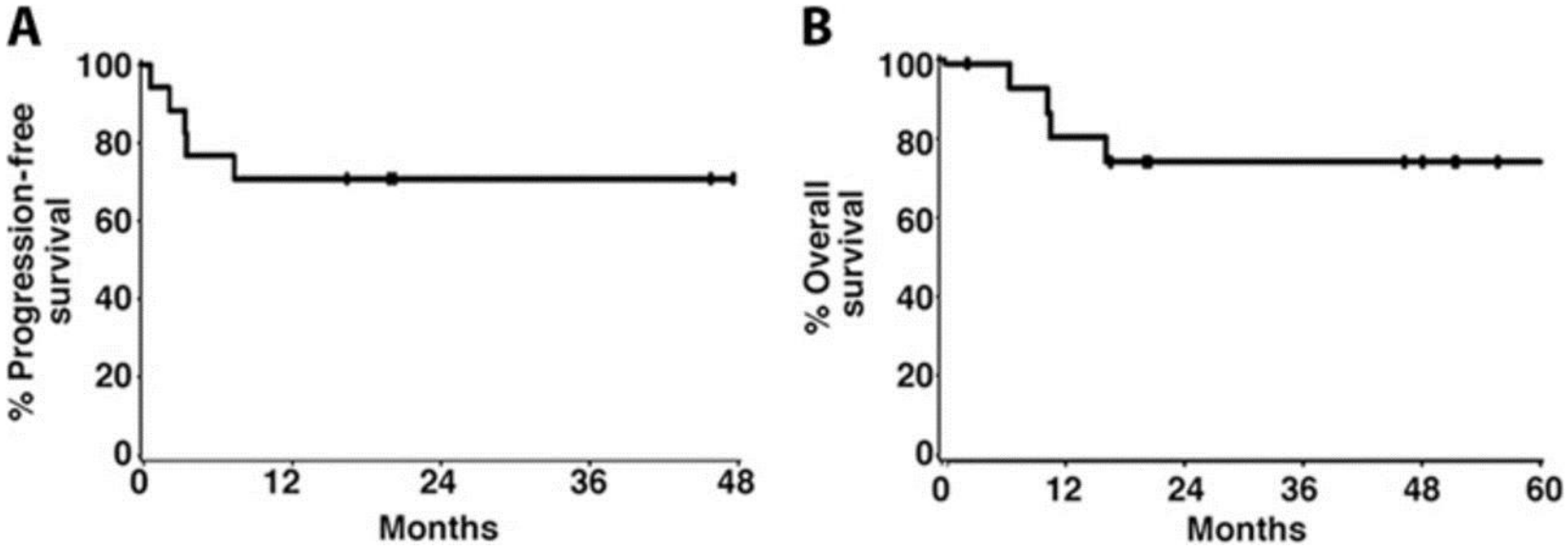
Expansion of leukemia-specific CD4+ and CD8+ T cells after vaccination



Sci Transl Med 2016;8:368ra171

Clinical Outcome



- 12 of 17 patients who received at least one dose of vaccine remain alive and in remission (**71%**; 90% CI, 52 to 89%) at 16.7 to 66.5 months from initiating vaccination
- **Median follow-up: 57 months**

Published by AAAS

Sci Transl Med 2016;8:368ra171

Clinical Outcome: Patient 11

04/2010
76 year old lady, presents with AML

Cytogenetics: +8, inv16
Hypomethylating agent +mylotarg
Ara-C 1 gram/m2 x 5 days

05/2010- REMISSION

03/2011- RELAPSE- enrolled on protocol

Cytogenetics: +8, inv 16, newly acquired +21
MEC – **Remission**
Ara-C 1 gram/m2 x 5 days

2 DOSES OF DC/AML fusion cell vaccine → **ONGOING REMISSION**

PRESENTLY
82 years old

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Resources:

Boyiadzis *et al. Journal for ImmunoTherapy of Cancer* (2016) 4:90
DOI 10.1186/s40425-016-0188-z

Journal for ImmunoTherapy of Cancer

POSITION ARTICLE AND GUIDELINES Open Access

The Society for Immunotherapy of Cancer consensus statement on immunotherapy for the treatment of hematologic malignancies: multiple myeloma, lymphoma, and acute leukemia

Michael Boyiadzis[1†], Michael R. Bishop[2†], Rafat Abonour[3], Kenneth C. Anderson[4], Stephen M. Ansell[5], David Avigan[6], Lisa Barbarotta[7], Austin John Barrett[8], Koen Van Besien[9], P. Leif Bergsagel[10], Ivan Borrello[11], Joshua Brody[12], Jill Brufsky[13], Mitchell Cairo[14], Ajai Chari[12], Adam Cohen[15], Jorge Cortes[16], Stephen J. Forman[17], Jonathan W. Friedberg[18], Ephraim J. Fuchs[19], Steven D. Gore[20], Sundar Jagannath[12], Brad S. Kahl[21], Justin Kline[22], James N. Kochenderfer[23], Larry W. Kwak[24], Ronald Levy[25], Marcos de Lima[26], Mark R. Litzow[27], Anuj Mahindra[28], Jeffrey Miller[29], Nikhil C. Munshi[30], Robert Z. Orlowski[31], John M. Pagel[32], David L. Porter[33], Stephen J. Russell[5], Karl Schwartz[34], Margaret A. Shipp[35], David Siegel[36], Richard M. Stone[4], Martin S. Tallman[37], John M. Timmerman[38], Frits Van Rhee[39], Edmund K. Waller[40], Ann Welsh[41], Michael Werner[42], Peter H. Wiernik[43] and Madhav V. Dhodapkar[44*]

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