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University of Nebraska Medical Center

Bio Ascend

VIRTUAL CHALLENGING CASE CLINIC:

Multiple Myeloma

CAR T Cells for MM

Broadcast on April 21, 2021

Course Director

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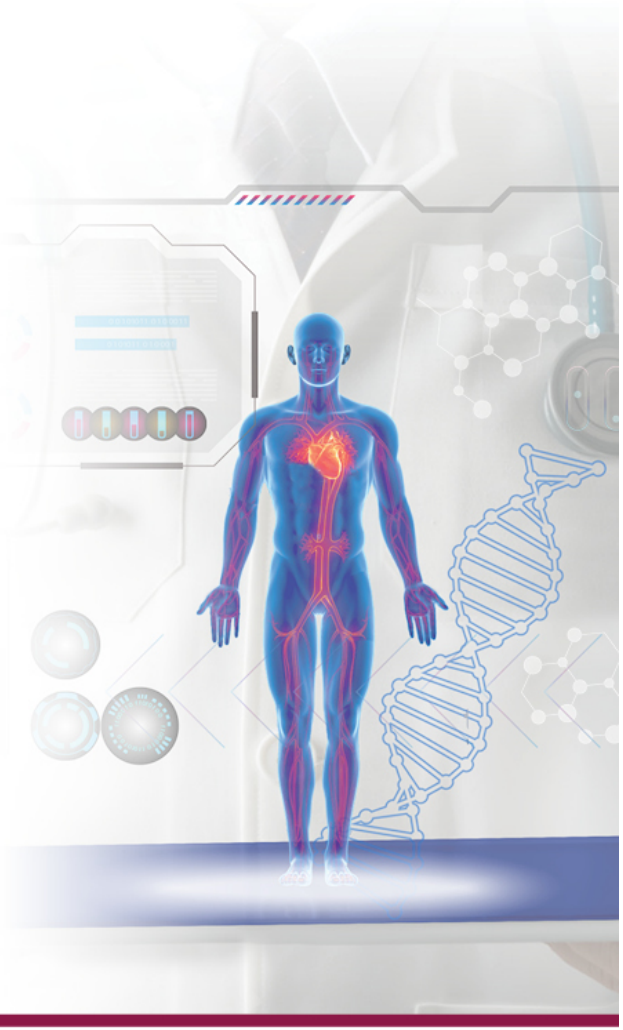
This activity is supported by independent educational grants from Bristol-Myers Squibb and Oncopeptides



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Disclosures

Sagar Lonial, MD, FACP

Consulting Fees: Amgen Inc., Bristol-Myers Squibb Company, Celgene Corporation, GlaxoSmithKline LLC, Janssen Oncology, Karyopharm Therapeutics, Merck & Co., Novartis

Nina Shah, MD

Consulting Fees: bluebird bio, Inc., Celgene Corporation, Janssen Oncology, Sutro Biopharma, Inc., TeneoBio

Contracted Research & Publishing: Amgen Inc., Bristol Myers Squibb, CareDx, Genentech, Inc., GlaxoSmithKline LLC, Indapta Therapeutics, Nektar Therapeutics, Precision BioSciences, Sanofi, Surface Oncology

Planning Committee

The following planning committee members have nothing to disclose:
UNMC: Brenda Ram, CMP, CHCP

Bio Ascend: Patti Bunyasaranand, MS; Dru Dace, PhD; Lucja Grajkowska, PhD; Kraig Steubing

Learning Objectives

- Evaluate best available evidence regarding the treatment of patients with multiple myeloma
- Assess the implications of emerging clinical trial data regarding multiple myeloma treatment approaches
- Develop strategies to address complicated multiple myeloma cases

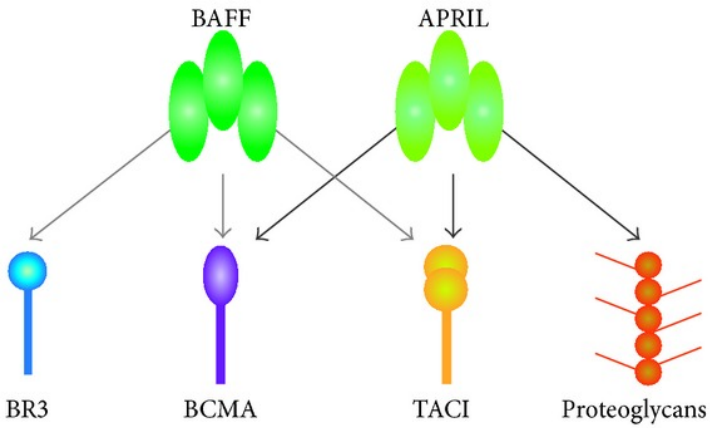
Case Presentation

- 62 YO M with R-ISS stage II myeloma
- Treatment: VRD induction→ASCT→ len maintenance: CR
- 3 y: PD→ DPD: VGPR
- 1 y: new L2 plasmacytoma and rising M protein→ KCD
- 7 mo: PD
- Overall good health with grade 1 neuropathy at toes

Discussion points

- Is this patient a good candidate for CAR T cell therapy?
- What the mechanism of action of CAR T cells?
- What can we tell the patient about the chance of success?

BCMA: B cell maturation antigen



- Member of TNFR (TNFRS17)
- Regulate B cell proliferation and survival, maturation to plasma cells
- Expression/ activation associated with myeloma cell growth/ survival
- Exclusively expressed on the surface of plasmablasts and differentiated PCs

Cho et al, *Frontiers in Immunol,* 2018
Tobon et al, *Autoimm Dis,* 2013

2020 ASCO ANNUAL MEETING
UNITE AND CONQUER: ACCELERATING PROGRESS TOGETHER

KarMMa™

Idecabtagene vicleucel (ide-cel, bb2121), a BCMA-targeted CAR T cell therapy, in patients with relapsed and refractory multiple myeloma (RRMM): initial KarMMa results

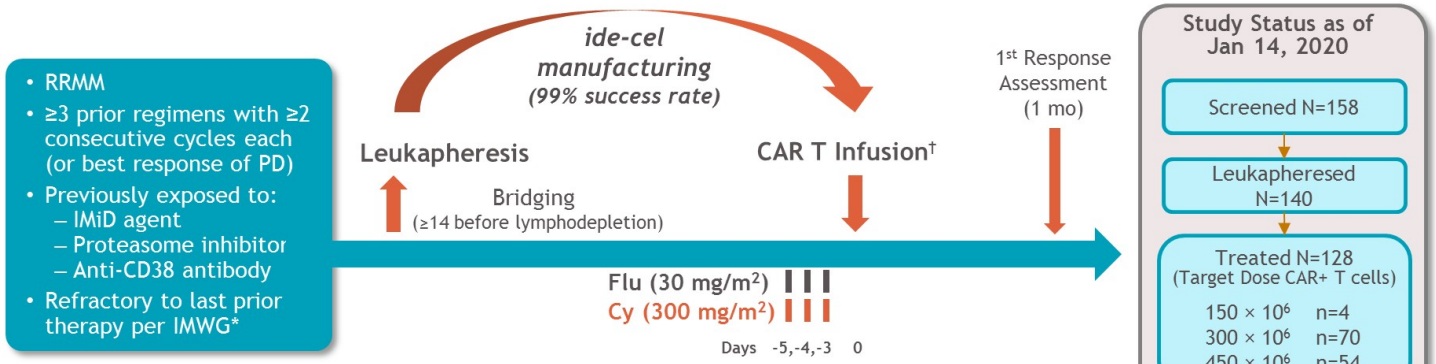
Nikhil C. Munshi, MD[1]; Larry D. Anderson, Jr, MD, PhD[2]; Nina Shah, MD[3]; Sundar Jagannath, MD[4]; Jesus Berdeja, MD[5]; Sagar Lonial, MD[6]; Noopur Raje, MD[7]; David S. Siegel, MD, PhD[8]; Yi Lin, MD, PhD[9]; Albert Oriol, MD[10]; Philippe Moreau, MD[11]; Ibrahim Yakoub-Agha, MD, PhD[12]; Michel Delforge, MD[13]; Fabio Petrocca, MD[14]; Jamie N. Connarn, PhD[15]; Payal Patel[15]; Liping Huang, PhD[15]; Timothy B. Campbell, MD, PhD[15]; Kristen Hege, MD[15]; and Jesus San Miguel, MD, PhD[16] *on behalf of the KarMMa study investigators*

[1]The LeBow Institute for Myeloma Therapeutics and Jerome Lipper Multiple Myeloma Center, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA; [2]Simmons Comprehensive Cancer Center, UT Southwestern Medical Center, Dallas, TX, USA; [3]University of California San Francisco, San Francisco, CA, USA; [4]Mount Sinai Hospital, New York, NY, USA; [5]Sarah Cannon Research Institute and Tennessee Oncology, Nashville, TN, USA; [6]Emory School of Medicine, Atlanta, GA, USA; [7]Massachusetts General Hospital, Boston, MA, USA; [8]Hackensack University Medical Center, Hackensack, NJ, USA; [9]Mayo Clinic, Rochester, MN, USA; [10]Institut Josep Carreras and Institut Catala d'Oncologia, Hospital Germans Trias i Pujol, Badalona, Spain; [11]Centre Hospitalier Universitaire de Nantes, Nantes, France; [12]Centre Hospitalier Regional Universitaire de Lille, Lille, France; [13]University Hospital Leuven, Leuven, Belgium; [14]bluebird bio, Cambridge, MA, USA; [15]Bristol Myers Squibb, Princeton, NJ, USA; and [16]Clinical Universidad de Navarra, Navarra, Spain

Presentation Number 8503

Presented By Nikhil Munshi at ASCO 2020

Phase II Pivotal KarMMa Study



Endpoints

- **Primary**: ORR (null hypothesis ≤50%)
- **Secondary:** CRR (key secondary; null hypothesis ≤10%), Safety, DOR, PFS, OS, PK, MRD‡, QOL, HEOR
- **Exploratory:** Immunogenicity, BCMA expression/loss, cytokines, T cell immunophenotype, GEP in BM

Study Status as of Jan 14, 2020

Screened	N=158
Leukapheresed	N=140
Treated (Target Dose CAR+ T cells)	N=128
150 × 10⁶	n=4
300 × 10⁶	n=70
450 × 10⁶	n=54

Median Follow-up (mo)

150 × 10⁶	18.0
300 × 10⁶	15.8
450 × 10⁶	12.4
Total	13.3

CRR, complete response rate; Cy, cyclophosphamide; DOR, duration of response; Flu, fludarabine; GEP in BM, gene expression profile in bone marrow; HEOR, health economics and outcomes research; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; MRD, minimal residual disease; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PK, pharmacokinetics; QOL, quality of life.
*Defined as documented disease progression during or within 60 d from last dose of prior antimyeloma regimen. †Patients were required to be hospitalized for 14 d post-infusion. Ide-cel retreatment was allowed at disease progression for best response of at least stable disease. ‡By next-generation sequencing.

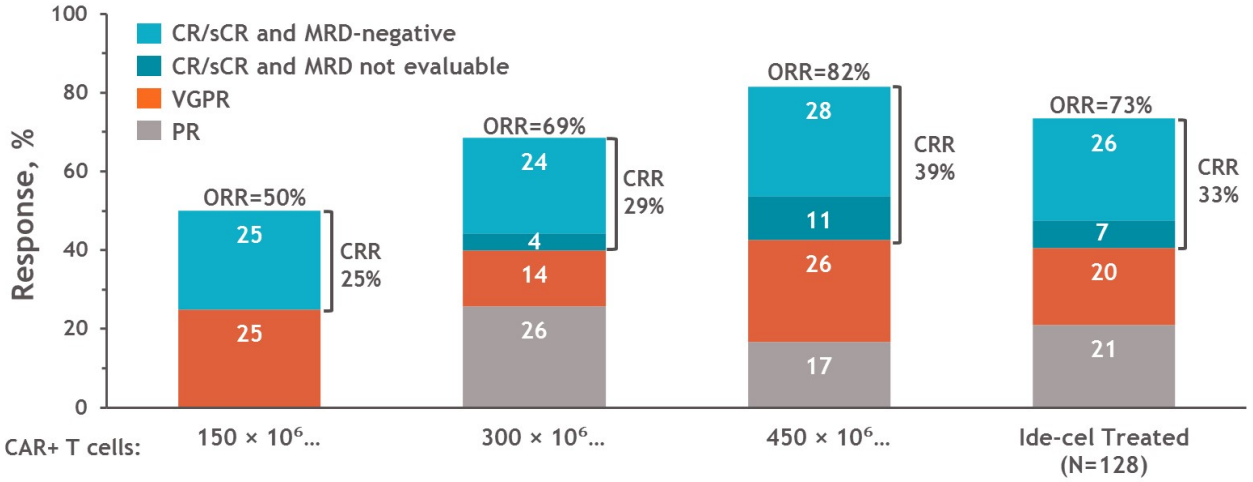
EudraCT: 2017-002245-29
ClinicalTrials.gov: NCT03361748

Best Overall Response

KarMMa™

Median # prior regimens: 6

CRS: 84%
Neurotox: 18%

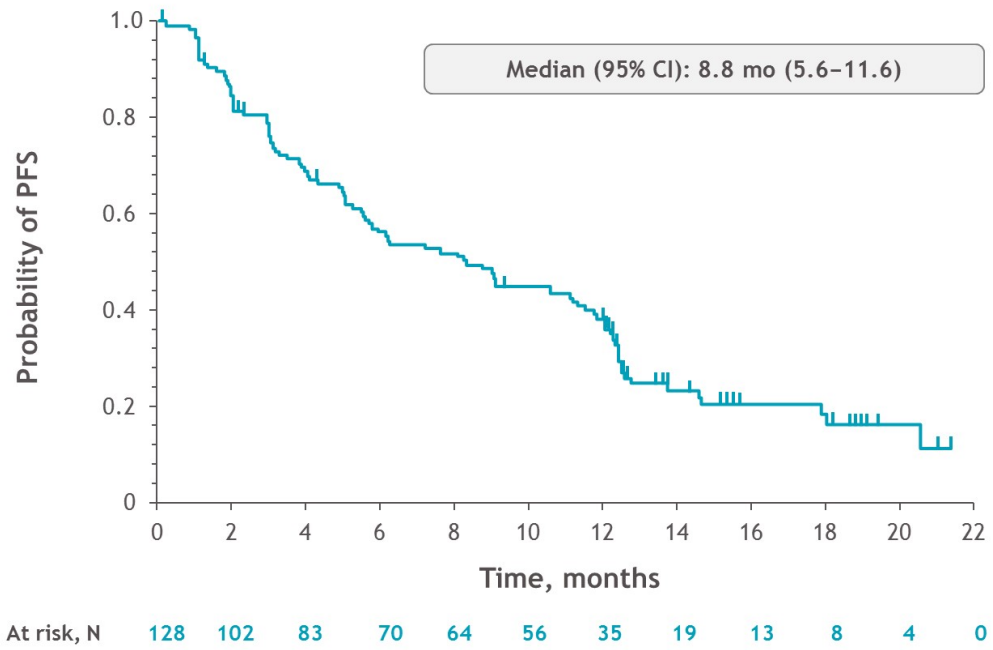


- Primary (ORR >50%) and key secondary (CRR >10%) endpoints met in the ide-cel treated population
  - *ORR of 73% (95% CI, 65.8–81.1; P<0.0001*)*
  - *CRR (CR/sCR) of 33% (95% CI, 24.7–40.9; P<0.0001)*
- Median time to first response of 1.0 mo (range, 0.5–8.8); median time to CR of 2.8 mo (range, 1.0–11.8)
- Median follow-up of 13.3 mo across target dose levels

Data cutoff: 14 Jan 2020. MRD-negative defined as $<10^{-5}$ nucleated cells by next generation sequencing. Only MRD values within 3 mo of achieving CR/sCR until progression/death (exclusive) were considered.
Values may not add up due to rounding.
CR/sCR, complete response/stringent CR; CRR, CR rate; MRD, minimal residual disease; ORR, overall response rate (≥PR); PR, partial response; VGPR, very good PR. **P* value at the primary data cutoff with same ORR and 95% CI.

Munshi et al, ASCO 2020

Progression-Free Survival



Data cutoff: 14 Jan 2020. PFS, progression-free survival.

Munshi et al, ASCO 2020

Progression-Free Survival

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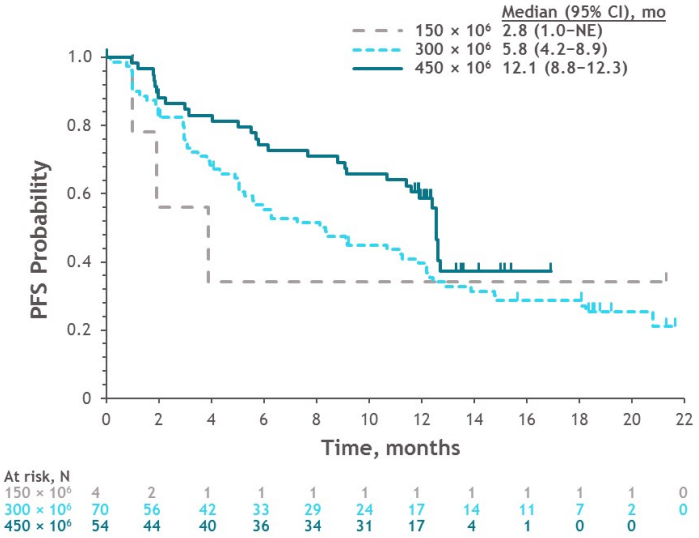
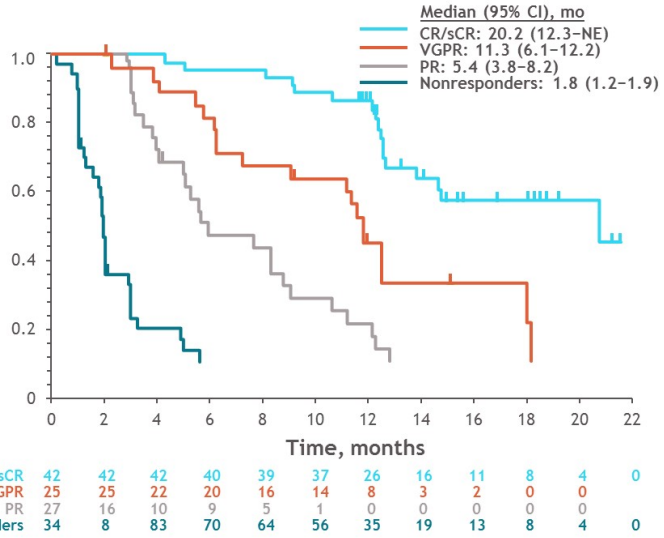
PFS by Target Dose



- PFS increased with higher target dose; median PFS was 12 mo at 450 × 10^6 CAR+ T cells

PFS by Best Response



- PFS increased by depth of response; median PFS was 20 mo in patients with CR/sCR

Data cutoff: 14 Jan 2020. NE, not estimable; PFS, progression-free survival.

Munshi et al, ASCO 2020

CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-Cell Maturation Antigen–Directed Chimeric Antigen Receptor T-Cell Therapy, in Relapsed/Refractory Multiple Myeloma

Deepu Madduri[1], Jesus G Berdeja[2], Saad Z Usmani[3], Andrzej Jakubowiak[4], Mounzer Agha[5], Adam D Cohen[6], A Keith Stewart[7], Parameswaran Hari[8], Myo Htut[9], Elizabeth O'Donnell[10], Nikhil C Munshi[11], David Avigan[12], Abhinav Deol[13], Alexander Lesokhin[14], Indrajeet Singh[15], Enrique Zudaire[15], Tzu-Min Yeh[16], Alicia J Allred[15], Yunsi Olyslager[17], Arnob Banerjee[15], Jenna D Goldberg[16], Jordan M Schecter[16], Carolyn C Jackson[16], William Deraedt[17], Sen Hong Zhuang[16], Jeffrey Infante[16], Dong Geng[18], Xiaoling Wu[18], Marlene J Carrasco-Alfonso[18], Muhammad Akram[18], Farah Hossain[18], Syed Rizvi[18], Frank Fan[19], Sundar Jagannath[1], Yi Lin[20], Thomas Martin[21]

[1]Mount Sinai Medical Center, New York, NY, USA; [2]Sarah Cannon Research Institute, Nashville, TN, USA; [3]Levine Cancer Institute-Atrium Health, Charlotte, NC, USA; [4]University of Chicago, Chicago, IL, USA; [5]UPMC Hillman Cancer Center, Pittsburgh, PA, USA; [6]Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA, USA; [7]UHN and the Princess Margaret Cancer Centre, Toronto, ON, Canada; [8]Medical College of Wisconsin, Milwaukee, WI, USA; [9]City of Hope Comprehensive Cancer Center, Duarte, CA, USA; [10]Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA; [11]Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA; [12]Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, USA; [13]Karmanos Cancer Institute, Wayne State University, Detroit, MI, USA; [14]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [15]Janssen R&D, Spring House, PA, USA; [16]Janssen R&D, Raritan, NJ, USA; [17]Janssen R&D, Beerse, Belgium; [18]Legend Biotech USA, Inc, Piscataway, NJ, USA; [19]Nanjing Legend Biotechnology Co, Ltd, Nanjing, China; [20]Mayo Clinic, Rochester, MN, USA; [21]UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA, USA

PRESENTED AT THE 62ND AMERICAN SOCIETY OF HEMATOLOGY (ASH) ANNUAL MEETING & EXPOSITION; DECEMBER 5–8, 2020 PRESENTATION #177

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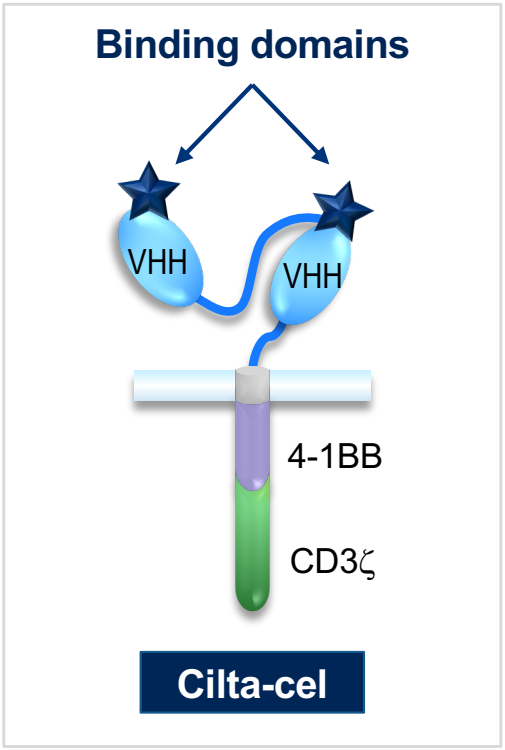
CARTITUDE-1: Introduction

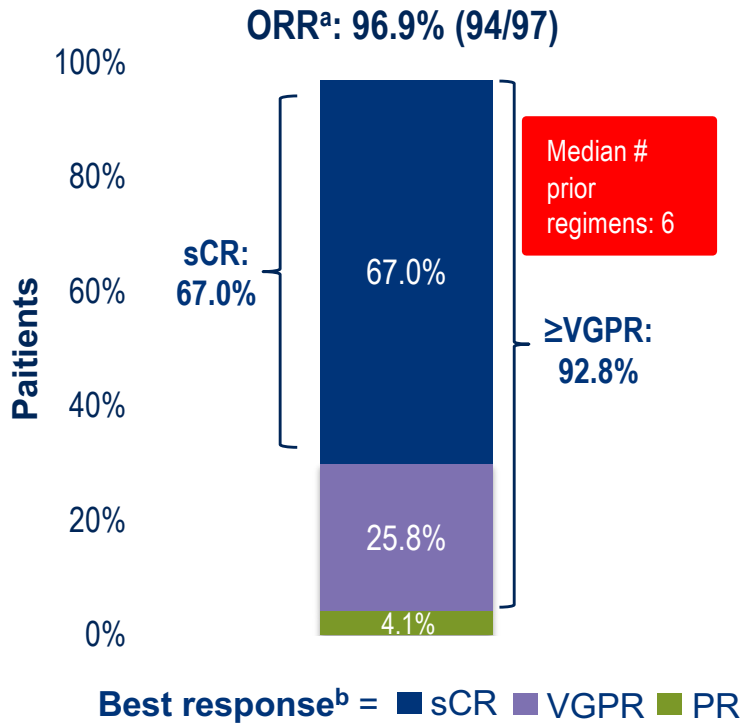


- Ciltacabtagene autoleucel (cilta-cel; JNJ-68284528) is a chimeric antigen receptor T-cell therapy
  - 2 BCMA-targeting single-domain antibodies designed to confer avidity
- In the phase 1b portion of the CARTITUDE-1 study, cilta-cel yielded deep, durable responses with a manageable safety profile in patients with relapsed/refractory MM[1]
- Here, we report initial results from the combined phase 1b/2 CARTITUDE-1 study of cilta-cel

BCMA, B-cell maturation antigen; MM, multiple myeloma; VHH, single variable domain on a heavy chain.

1. Berdeja J, et al. *J Clin Oncol* 2020;38(Suppl):8505.

CARTITUDE-1: ORR and MRD Assessment



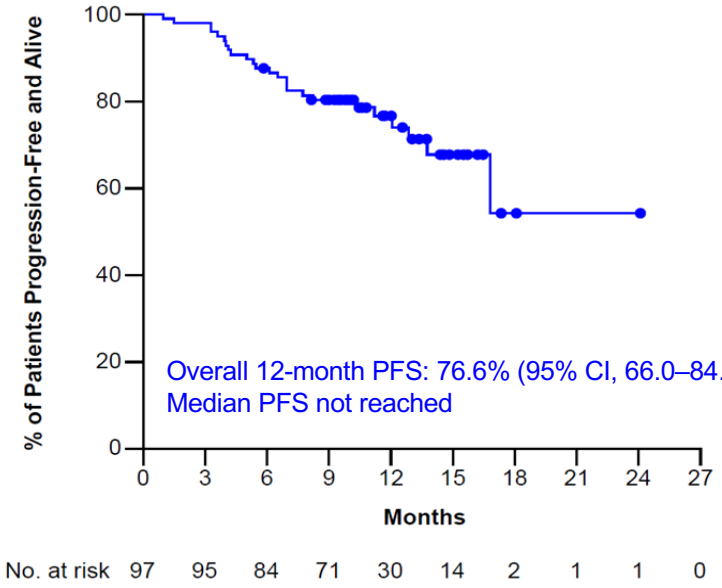
	N	Frequency in evaluable patients n=57[c]	Frequency in all treated n=97[d]
Overall MRD-	53	93.0%	54.6%
MRD- and sCR	33	57.9%	34.0%
MRD- and ≥VGPR	49	86.0%	50.5%

- Median time to first response: 1 month (0.9–8.5)
- Responses ongoing in 70 (72.2%) patients
- Of evaluable patients, 93.0% achieved MRD 10^{-5} negativity
  - Median time to MRD 10^{-5} negativity: 1 month (0.8–7.7)
- Among patients with 6 months individual follow-up, most had cilta-cel CAR+ T cells below the level of quantification (2 cells/μL) in peripheral blood

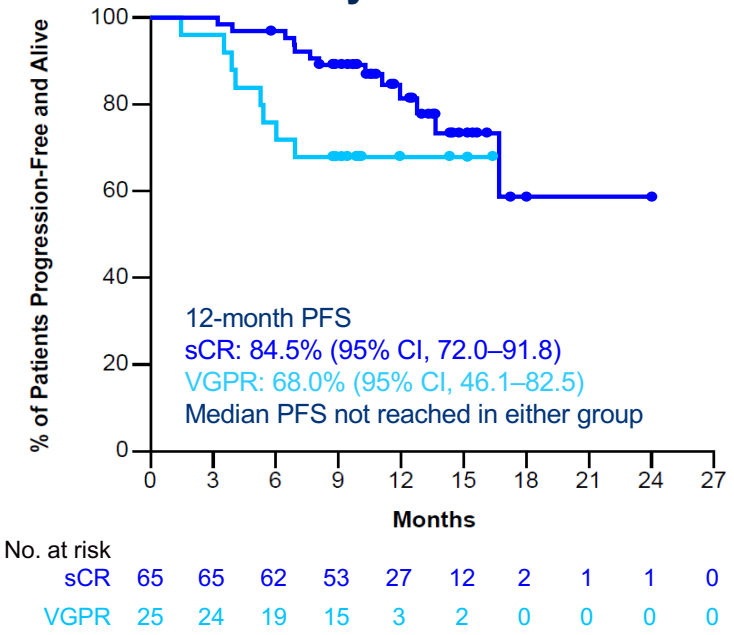
CAR, chimeric antigen receptor; CR, complete response; MRD, minimal residual disease; ORR, overall response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response. [a]PR or better, Independent Review Committee assessed. [b]No patient had CR or stable disease as best response. [c]MRD was assessed in evaluable samples at 10^{-5} threshold by next-generation sequencing (clonoSEQ, Adaptive Biotechnologies) in all treated patients at Day 28, and at 6, 12, 18, and 24 months regardless of the status of disease measured in blood or urine; patients were not evaluable primarily due to lack of an identifiable clone in the baseline bone marrow sample. [d]All treated patients.

CARTITUDE-1: PFS

Overall PFS



PFS by sCR and VGPR



At median duration of follow-up of 12.4 months (range, 1.5–24.9), median PFS has not been reached
12-month PFS rate: 76.6% (95% CI, 66.0–84.3)
12-month OS rate: 88.5% (95% CI, 80.2–93.5)

OS, overall survival; PFS, progression-free survival; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

House of CARs

Trial	Company	CAR T product	Med prior lines	Special Sauce	ORR	CRS %	Neurotox %	Survival data	Notes
Karmma-1 (phase II, n=128)	Celgene/ BMS	Bb2121 (Ide-cel)	6		73% (82% @450 dose)	84%	18%	mPFS 8.8mo, 12.1 mo @450 dose	CAR-T Par-T in mid 2021!!
CARTITUDE-1 (phase Ib/II, n-97)	Janssen	JNJ-4528 (Ciltacel)	6	Bi-epitope binding to BCMA	97%	92%	20% (16.5% ICANS)	@ 12 mo: 77% prog-free	Google to the yahoo?
LUMMICAR-2 (phase Ib/II, n=18-20)	CARSgen	CT053	5	Fully human	94% (n=18)	77-83%	15-17%	NA	
PRIME (phase I/II, n=55)	Poseida	P-BCMA-101	8	Piggy-bac system, centyrin technology	67% w/ nanoplasmid (n=6); 44-75% w/OG mfg (n=30)	17%	3.8%	NA	
CRB-402 (phase I, n-69)	Bluebird	bb21217	6	PI3Ki culture to increase Tscm cells	68% (73% at 450 dose, 84% w/ new mfg)	70%	16%	mDOR 17 mo (all doses)	Memory cell phenptype in DP may correlate w/ response
UNIVERSAL (phase I, n=26-31)	Allogene	Allo-715	5	Allo CART	60-67% at 320 dose	45%	0	NA	Variability in LD, tx within 5 days of enrollment!! No GVH

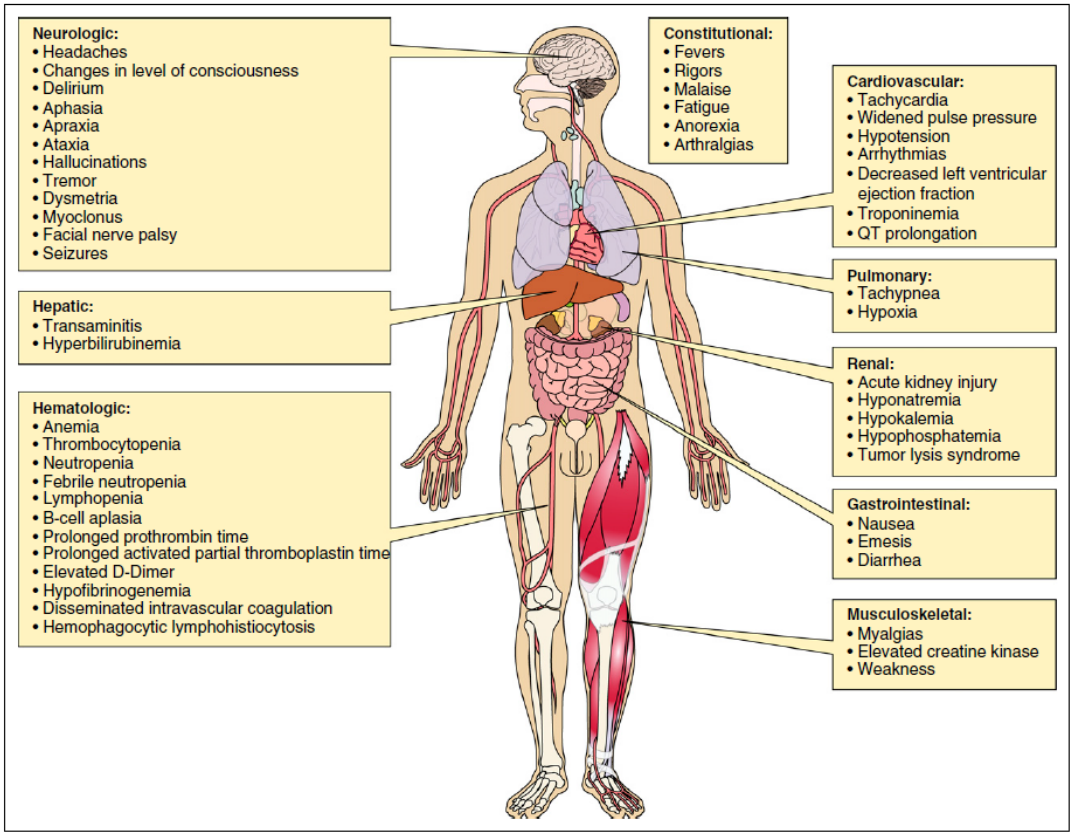
Case Presentation

- Our patient undergoes treatment with BCMA CAR T
- 24 h after infusion of T cells he has fever to 38.5, BP 106/66
- Feels fatigued
- CRP = 3.6→ 72.8
- Receives acetaminophen→ fever recurs, BP now 89/56

Discussion points

- What is cytokine release syndrome (CRS)?
- What grading criteria are used?
- How is CRS managed?
- What are other toxicities that may occur with CAR T cells?

CRS



Brudno, *Blood* 2016

Revised ASTCT Grading System

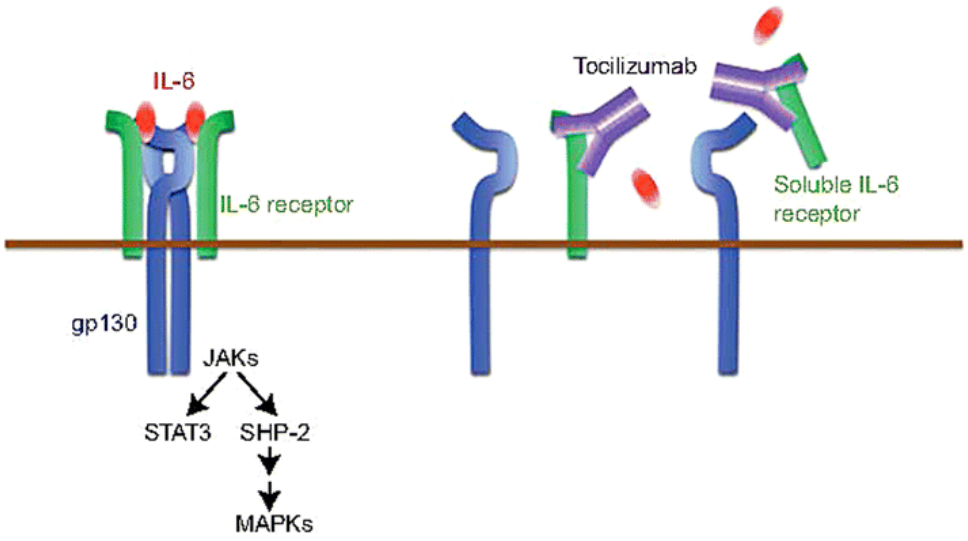
CRS Parameter	Grade 1	Grade 2	Grade 3	Grade 4
Fever*	Temperature ≥38°C	Temperature ≥38°C	Temperature ≥38°C	Temperature ≥38°C
		With		
Hypotension	None	Not requiring vasopressors	Requiring a vasopressor with or without vasopressin	Requiring multiple vasopressors (excluding vasopressin)
		And/or†		
Hypoxia	None	Requiring low-flow nasal cannula‡ or blow-by	Requiring high-flow nasal cannula‡, facemask, nonrebreather mask, or Venturi mask	Requiring positive pressure (eg, CPAP, BiPAP, intubation and mechanical ventilation)

Organ toxicities associated with CRS may be graded according to CTCAE v5.0 but they do not influence CRS grading.

- * Fever is defined as temperature 38°C not attributable to any other cause. In patients who have CRS then receive antipyretic or anticytokine therapy such as tocilizumab or steroids, fever is no longer required to grade subsequent CRS severity. In this case, CRS grading is driven by hypotension and/or hypoxia.
- CRS grade is determined by the more severe event: hypotension or hypoxia not attributable to any other cause. For example, a patient with temperature of 39.5°C, hypotension requiring 1 vasopressor, and hypoxia requiring low-flow nasal cannula is classified as grade 3 CRS.
- Low-flow nasal cannula is defined as oxygen delivered at 6 L/minute. Low flow also includes blow-by oxygen delivery, sometimes used in pediatrics. High-flow nasal cannula is defined as oxygen delivered at >6 L/minute.

Lee et al, *BBMT;* 2019

CRS management



- Supportive care
- Tocilizumab
- Steroids (dexamethasone)
- More steroids (methylprednisolone)
- Other
  - —Cyclophosphamide

CAR-T related neurotoxicity, *aka* ICANS:
Immune effector cell-associated neurotoxicity syndrome

- Delirium
- Encephalopathy
- Aphasia
- Lethargy
- Difficulty concentrating
- Agitation
- Tremor
- Seizures
- Cerebral edema
- (Headache)
- Usually after CRS
- CAR T cells
- Fever
- Hospitalization
- Dexamethasone
- Fludarabine

"…an awake patient who is mute and does not respond verbally or physically to an examiner"

Lee et al, *BBMT* 2019

ICANS Management

- Seizure prophylaxis
- Steroids (dexamethasone)
- Increase steroids
- Change steroids (methylprednisolone)
- Other
  - Consider cyclophosphamide

House of CARs

Trial	Company	CAR T product	Med prior lines	Special Sauce	ORR	CRS %	Neurotox %	Survival data	Notes
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Case Presentation

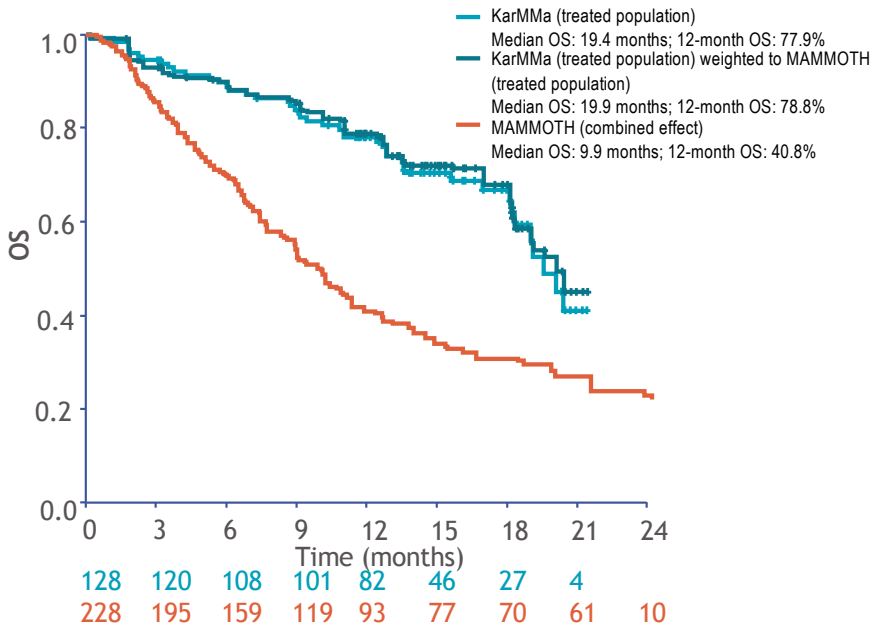
- 1 month after CAR T cell infusion KFLC 1200→ 46 mg/L
- M protein 1.8→ 1.3 g/dL
- Pt has required GCSF 2 x
- Grade 1 fatigue
- BM: no plasma cells detected; MRD pending

Discussion points

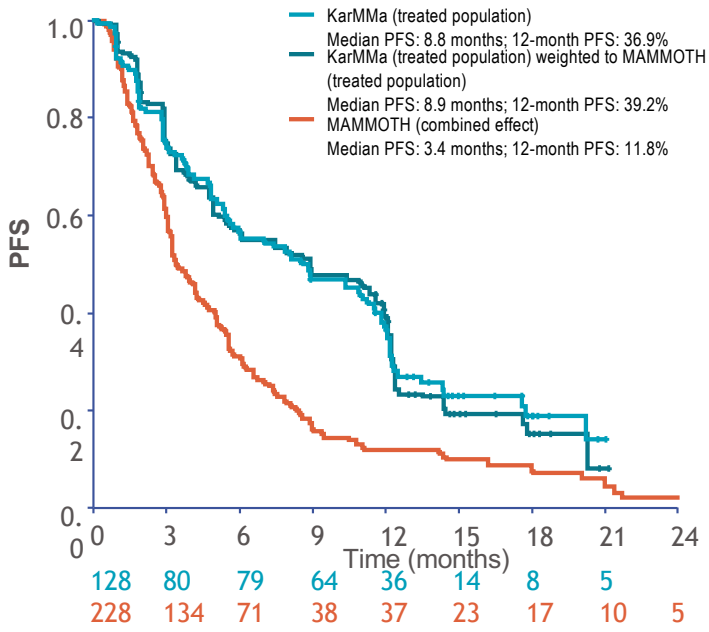
- How does the response to CAR T cells compare with other late line therapies?
- What are the effects on quality of life?
- How would the experience be different from other BCMA modalities?

OS and PFS: ide-cel versus conventional care

OS: Ide-cel (KarMMa treated population) versus conventional care (MAMMOTH treated population)



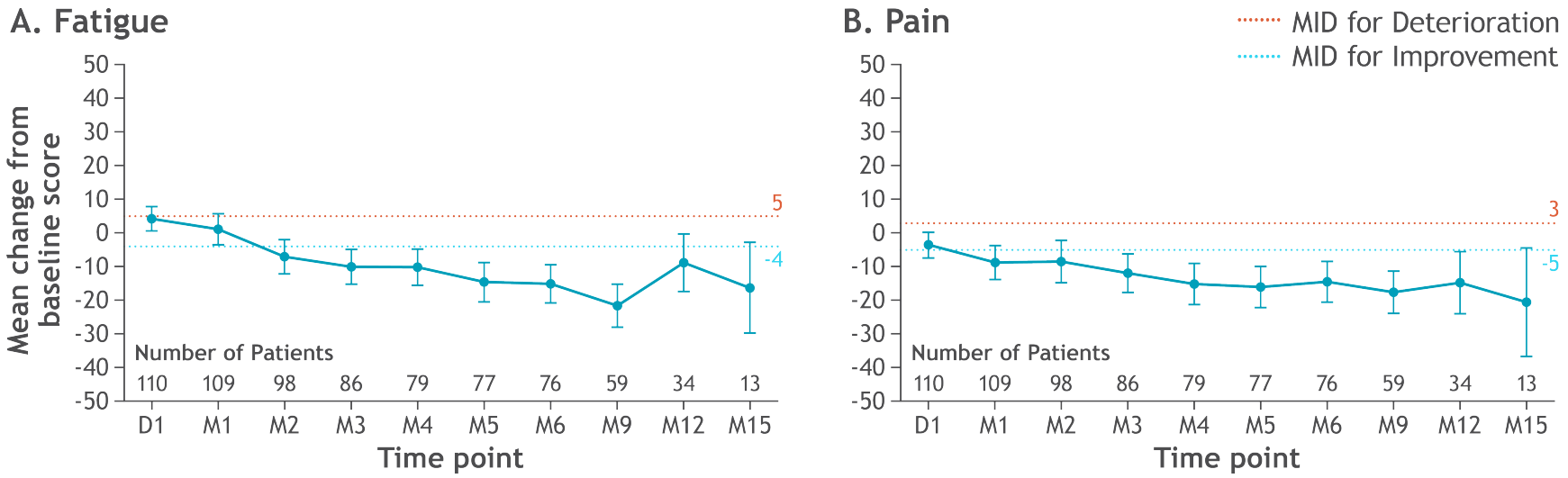
PFS: Ide-cel (KarMMa treated population) versus conventional care (MAMMOTH treated population)



- Median OS and median PFS were significantly longer for the ide-cel-treated population (weight-matched) compared with the conventional care population in MAMMOTH in the base case

Shah N, et al. ASH 2020 [abstract #1653]

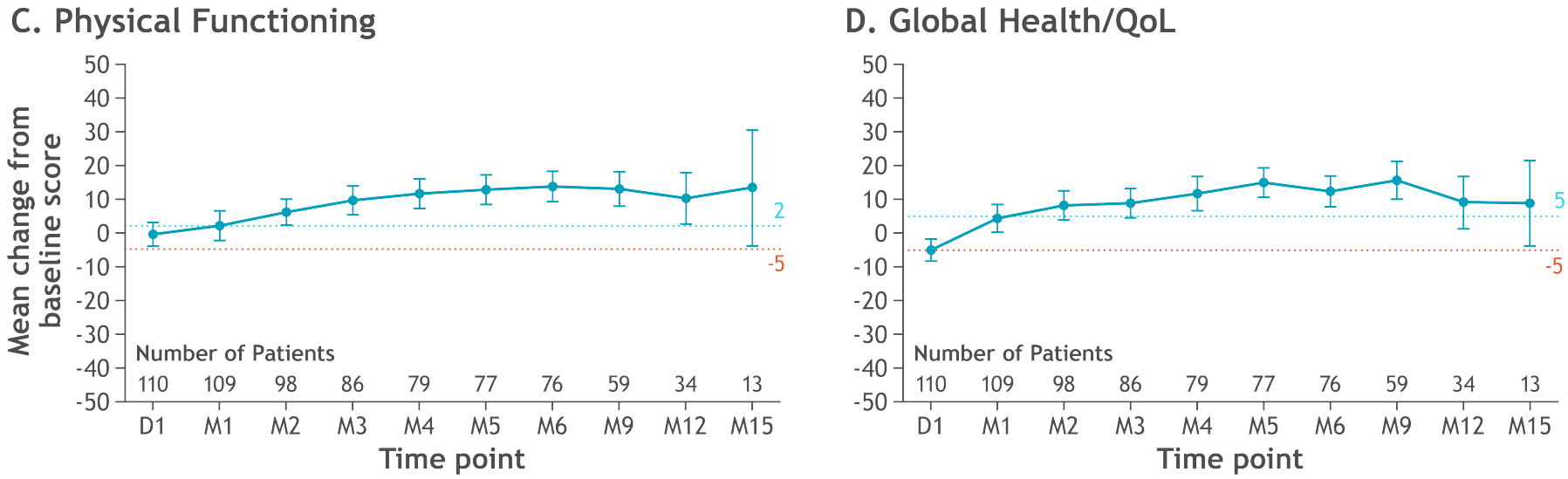
Figure 3. Mean change from baseline in EORTC QLQ-C30 subscale scores



D, day; M, month; MID, Minimal Important Difference.
Baseline defined as last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
Error bars represent 95% confidence intervals.

Delforge M et al; EHA 2020 #EP1000]

Figure 3. Mean change from baseline in EORTC QLQ-C30 subscale scores (Cont.)

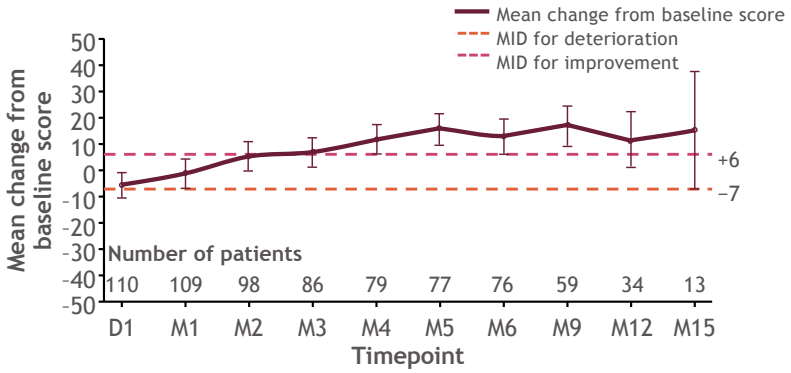


D, day; M, month; MID, Minimal Important Difference.
Baseline defined as last non-missing assessment on/prior to day of lymphodepleting chemotherapy.
Error bars represent 95% confidence intervals.

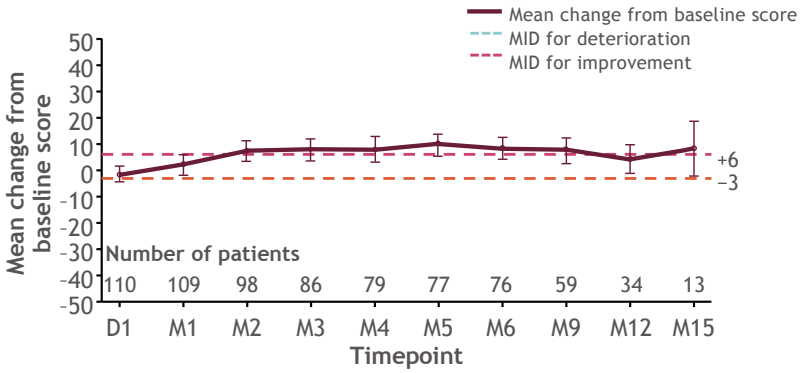
Delforge M et al; EHA 2020 #EP1000]

Clinically meaningful improvements were observed on all functioning EORTC QLQ-C30 secondary subscales

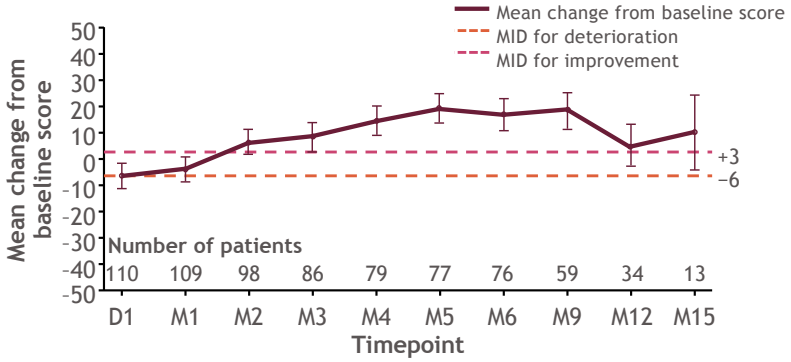
Role Functioning



Emotional Functioning



Social Functioning



- These improvements were statistically significant for the Role Functioning and Social Functioning subscales at multiple time points

Day 1 is day of infusion. Error bars denote 95% confidence intervals.
D1, Day 1; M, month; MID, minimal important difference.

Shah N, et al. ASH 2020 [abstract #437]

BCMA CAR T summary (ide-cel)

- Safety ✅
- Efficacy ✅
- PFS ✅
- Likely improvement of PFS over conventional care ✅
- QOL improvement ✅

FDA NEWS RELEASE

FDA Approves First Cell-Based Gene Therapy for Adult Patients with Multiple Myeloma

Comparing options

	CAR T	Bispecifics	ADCs
Treatment logistics	Specialized center, need to wait for production	TBA, likely community-friendly, off-the shelf Need for long-acting	Community-friendly, off-the shelf
Length of treatment	~2 months	??	Possibly limited cycles
Toxicities	CRS, neurotoxicity, cytopenias	CRS, pneumonia	Corneal, thrombocytopenia
Cost	? $400K	? But have to consider length of treatment	$24K/month

Conclusions

- CAR T therapy showing great promise in relapsed MM
- Impressive response rates
- Unprecedented survival data
- Patient experience overall good
- Insurers' experience….???
- Not curative yet! → Clinical trials are critical!!

THANK YOU!

@ninashah33
#myelennial

Thank You!

Visit OncologyCaseClinic.com to register for upcoming webinars.

Next presentation: Wednesday, June 16
Updates from ASCO and EHA
Presented by Jonathan Kaufman, MD