Neue Immuntherapien bei Multiplem Myelom

bispezifische Antikörper & CART-Zelltherapie

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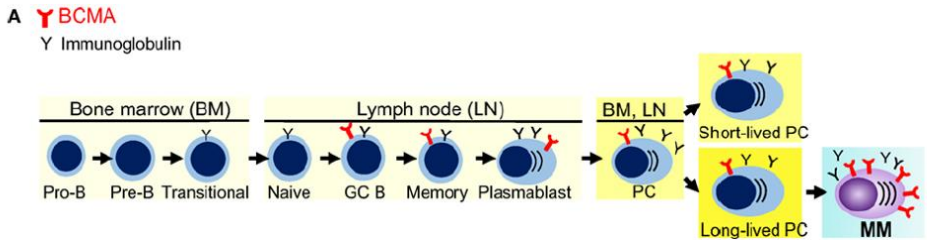
Interessenskonflikte

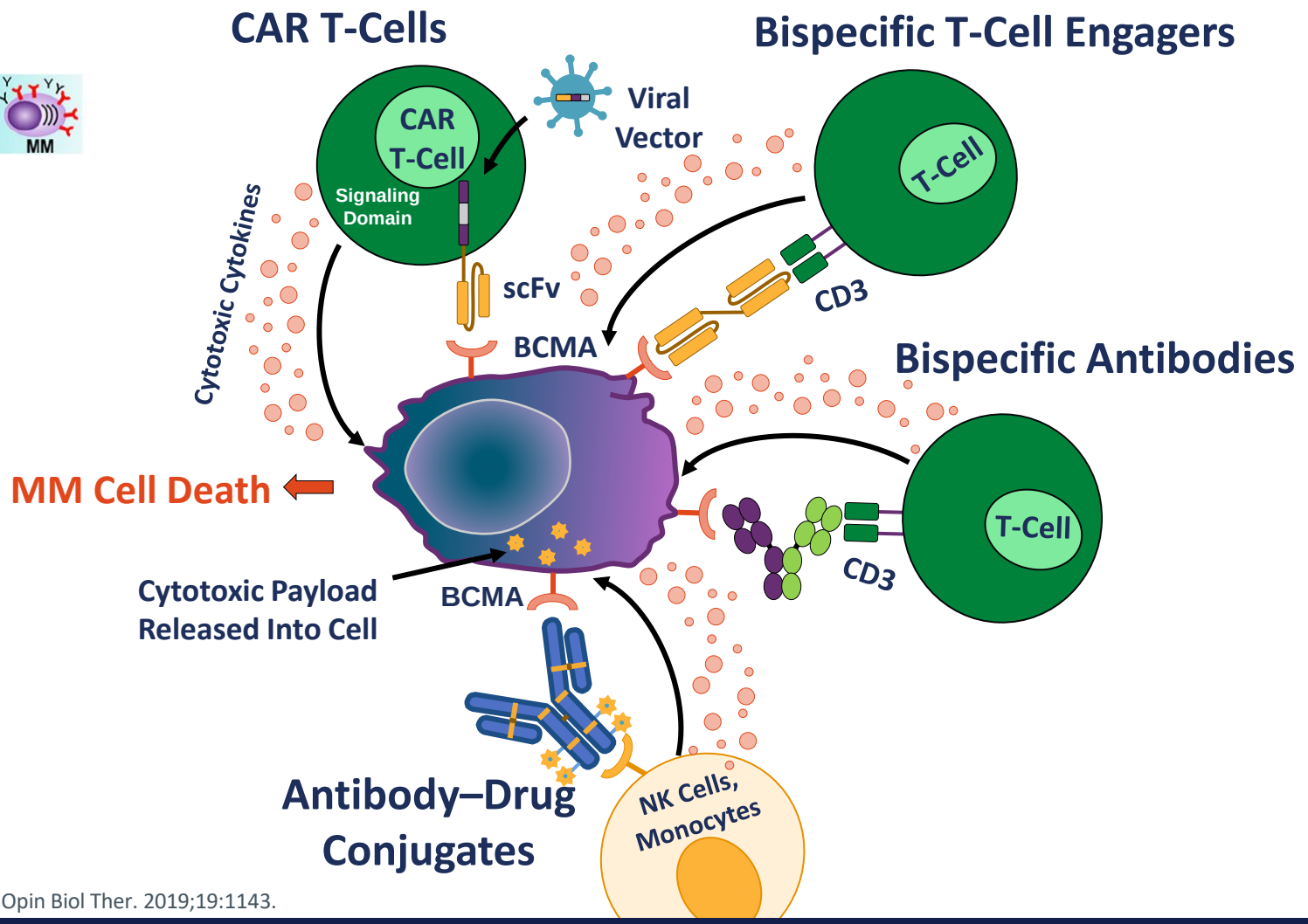
- Stockholder: nothing to disclose
- Employee: nothing to disclose
- Scientific Advisory boards and/or Honoraria:

  Amgen, BMS/Celgene, Janssen, Takeda, Novartis, Sanofi, GSK, Pfizer, Abbvie, Stemline, Oncopeptides

Immunotherapy Era in Multiple Myeloma

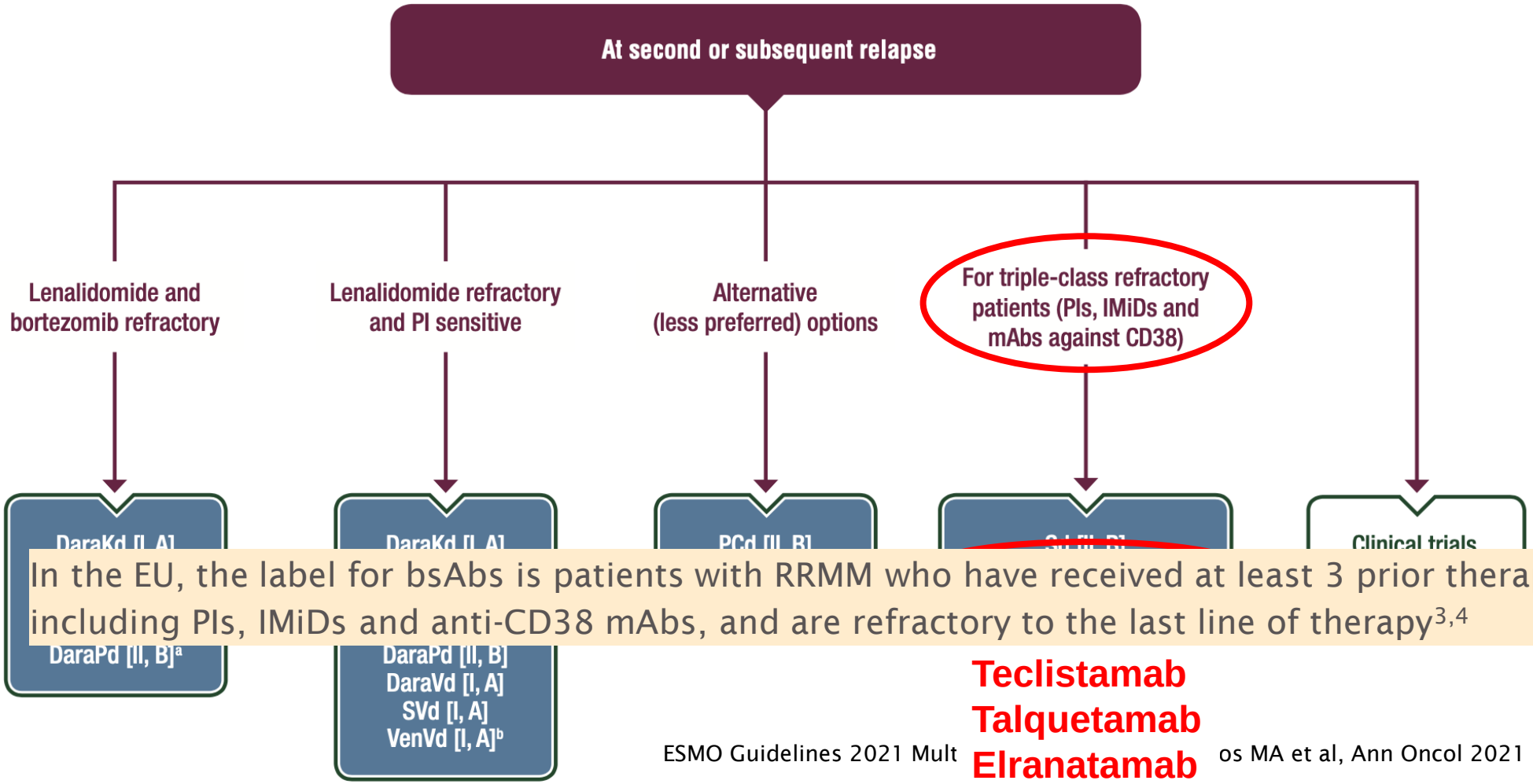


- **Antibody–drug conjugate**
  - Belantamab mafodotin-blmf
- **BCMA-directed CAR T-cell therapy**
  - Idecabtagene vicleucel
  - Ciltacabtagene autoleucel
- **Bispecific antibodies**
- **Naked antibodies**
- **Multiple targets**
  - BCMA
  - GPRC5D
  - FcHR5
  - SLAMF7



Cho. Front Immunol. 2018;9:1821. Su. J Hematol Oncol. 2021;14:115. Tai. Expert Opin Biol Ther. 2019;19:1143.

Triple class - refractory disease



In the EU, the label for bsAbs is patients with RRMM who have received at least 3 prior therapies including PIs, IMiDs and anti-CD38 mAbs, and are refractory to the last line of therapy[3,4]

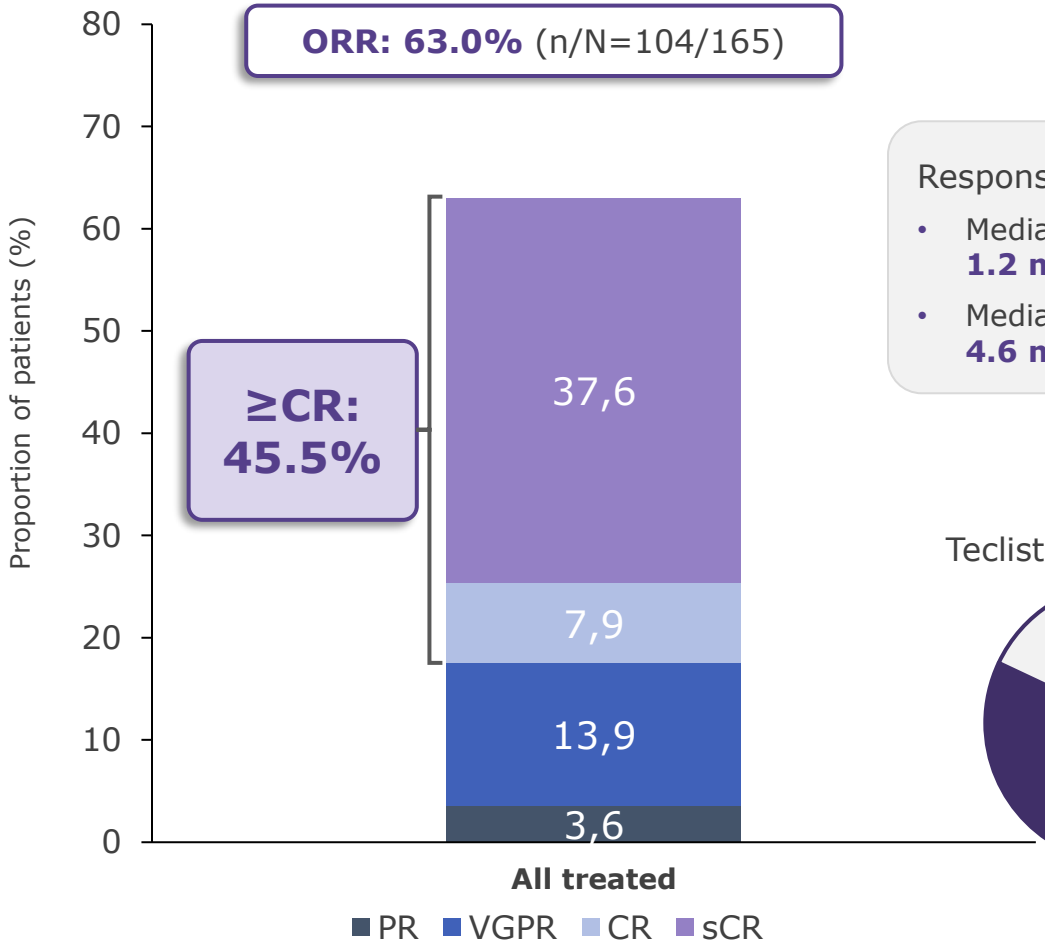
ESMO Guidelines 2021 Mult os MA et al, Ann Oncol 2021

Teclistamab
Talquetamab
Elranatamab
Cilta-Cel
Ide-Cel

Bispecific antibodies
(targets BCMA, GPRC5D)

TECVAYLI® (TECLISTAMAB) DELIVERS HIGH RATES OF RAPID, DEEP AND DURABLE RESPONSES AND IMPROVES HRQoL FOR TRIPLE-CLASS-EXPOSED PATIENTS WITH RRMM

MAJESTEC-1 study



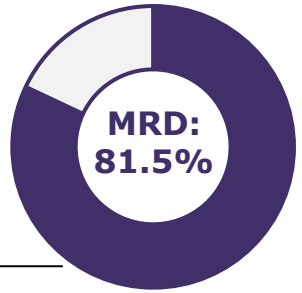
Responses occurred **early**:

- Median time to **first response**: **1.2 months** (range, 0.2–5.5)
- Median time to **≥CR**: **4.6 months** (range, 1.6–18.5)

Subgroup analyses

Consistent response rates were observed across **most clinically relevant subgroups**, including patients with **penta-drug-refractory disease** and those with **high-risk cytogenetic abnormalities**[3]

Teclistamab induced **deep responses**:



MRD negativity rate (at 10^{-5}) among MRD-evaluable patients (n/N=44/54)

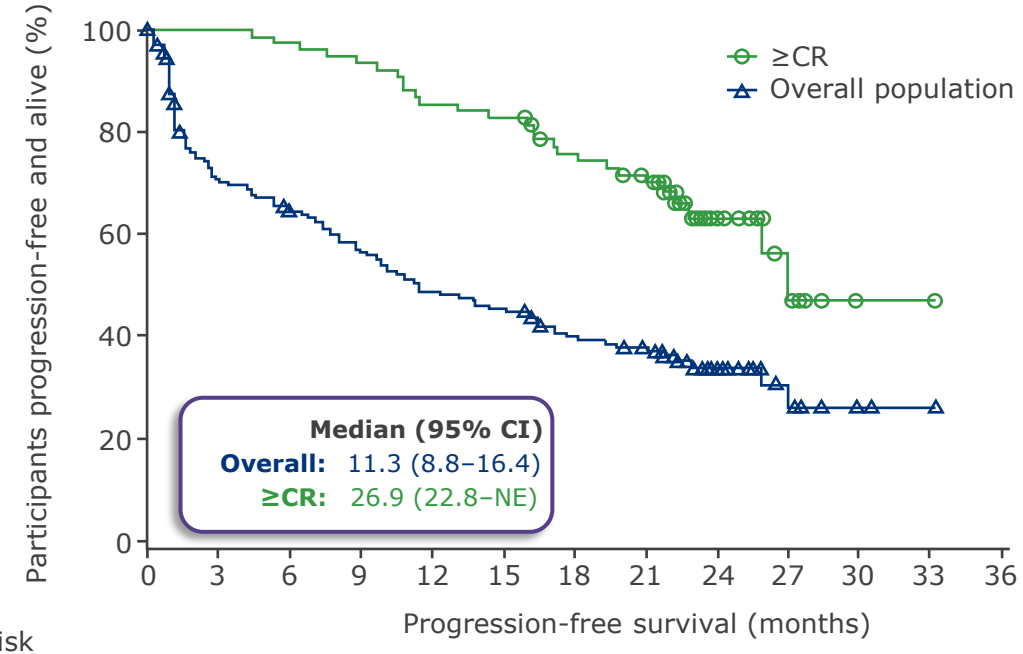
Teclistamab has the **longest reported follow-up (23 months)** for a bispecific antibody in MM to date

1. Van de Donk NWCJ, et al. ASCO 2023. Poster 8011; 2. Martin T, et al. ASCO 2022. Poster 8033; 3. Moreau P, et al. *N Engl J Med* 2022;387:495–505; 4. Touzeau C, et al. ASCO 2022. Poster 8013; 5. Usmani SZ, et al. ASCO 2023. Poster 8034; 6. Moreau P, et al. *N Engl J Med* 2022;387:495–505 (protocol).

TECVAYLI® (TECLISTAMAB) DELIVERS HIGH RATES OF RAPID, DEEP AND DURABLE RESPONSES AND IMPROVES HRQoL FOR TRIPLE-CLASS-EXPOSED PATIENTS WITH RRMM

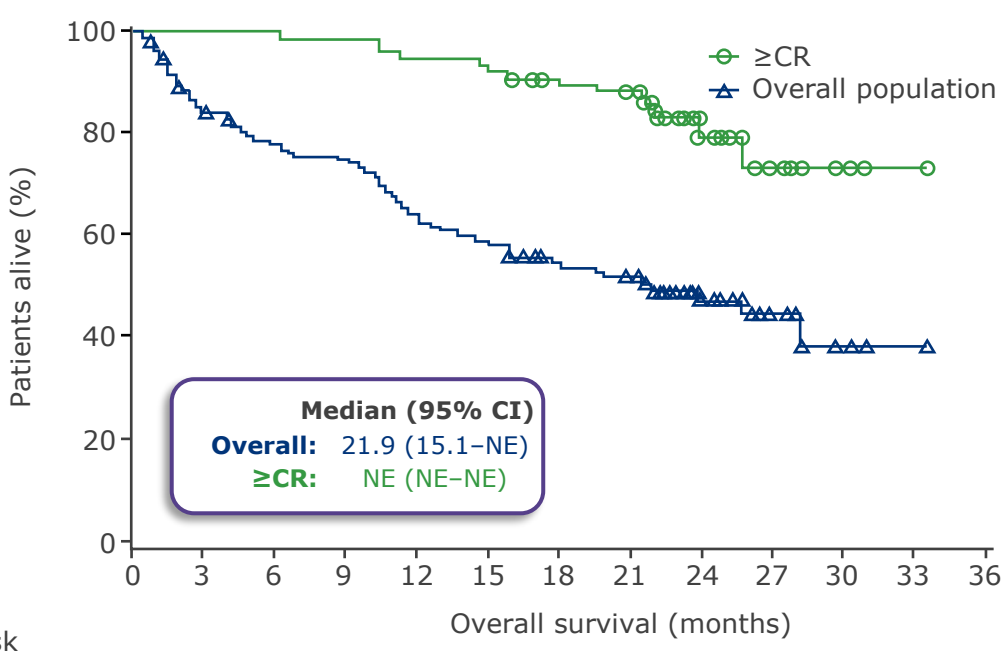
mPFS in patients who **achieved ≥CR** was **26.9 months** (95% CI: 22.8–NE); **mOS** in patients who **achieved ≥CR was not reached**

mPFS (N=165)



No. at risk													
≥CR	75	75	73	70	64	62	54	45	17	5	1	1	0
Overall	165	110	98	86	74	69	57	48	19	6	2	1	0

mOS (N=165)



No. at risk													
≥CR	75	75	75	74	71	70	65	62	23	8	3	1	0
Overall	165	136	124	119	102	93	81	76	29	11	4	1	0

*Data cut-off: 4 January 2023; median follow-up: 23 months.

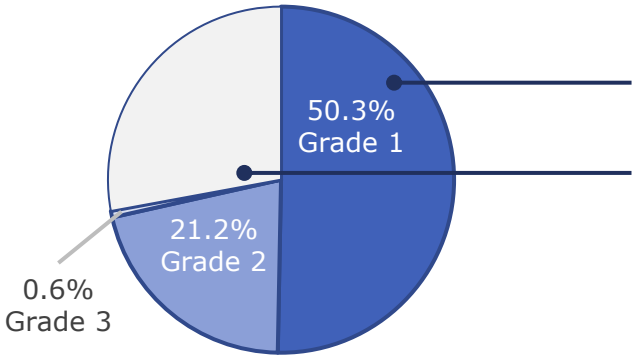
1. Van de Donk NWCJ, et al. ASCO 2023. Poster 8011 (including supplementary material); 2. Martin T, et al. ASCO 2022. Poster 8033; 3. Usmani SZ, et al. ASCO 2023. Poster 8034.

TECVAYLI®(TECLISTAMAB)THERAPY IS WELL TOLERATED AND OFFERS A PREDICTABLE AND MANAGEABLE SAFETY PROFILE

CRS events were predictable, manageable and generally mild in severity (predominantly Grade 1/2). All CRS events fully resolved without treatment discontinuation

72.1% **of patients (119/165) had a CRS event**

Maximum toxicity grade:



CRS events were predominantly **low grade (Grade 1/2)**

There was only one Grade 3 CRS event among 165 patients (0.6%; in a patient with concurrent pneumonia; time to resolution: 2 days)

The **majority** of CRS events occurred after **step-up and Cycle 1 doses**, with only six patients (3.6%) having CRS events in Cycle 2 or later[1]

Median duration:
2 days (range, 1–9)

Median time to onset after the most recent dose:
2 days (range, 1–6)

CRS mitigation

- **Step-up dosing** (Day 1: 0.06 mg/kg; Day 3: 0.3 mg/kg)
- **Pre-treatment medicinal products** administered prior to each teclistamab dose in the step-up dosing schedule
  - Corticosteroids
  - Antihistamines
  - Antipyretics

CRS management

Parameter	N=165
Received supportive measures† for CRS, n (%)	110 (66.7)
Tocilizumab	60 (36.4)
Low-flow oxygen by nasal cannula‡	21 (12.7)
Corticosteroids	14 (8.5)
Single vasopressor	1 (0.6)

*Assessed per the American Society for Transplantation and Cellular Therapy criteria; †A patient may have received >1 supportive therapy for CRS. Other supportive measures not listed include IV fluids ar

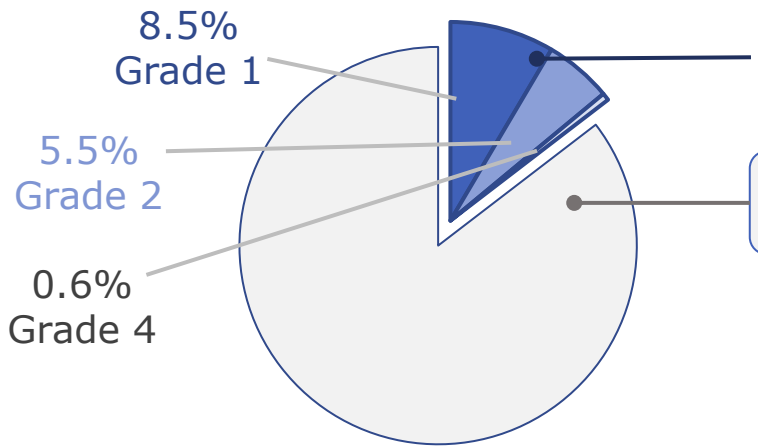
1. Moreau P, et al. *N Engl J Med* 2022;387:495–505 (and supplement); 2. Nooka A, et al. ASCO 2022. Oral presentation 8007; 3. Van de Donk NWCJ, et al. ASCO 2023. Poster 8011;
4. TECVAYLI® Fachinformation 08/2023

TECVAYLI®(TECLISTAMAB)THERAPY IS WELL TOLERATED AND OFFERS A PREDICTABLE AND MANAGEABLE SAFETY PROFILE

The overall incidence of neurotoxic events, including ICANS, was low with teclistamab therapy, and events were predominantly low grade (Grade 1/2). All neurotoxic events, including ICANS, fully resolved without treatment discontinuation

The incidence of neurotoxic events was low: 14.5% of patients (24/165)

Maximum toxicity grade:



Neurotoxic events were predominantly **low grade (Grade 1/2)**

The **majority** of patients (85.5%) did not experience a neurotoxic event

Median duration:
7 days (range, 1–291)

Median time to onset after the most recent dose:
3 days (range, 1–13)

Incidence of ICANS was low

3.0%
(n=5)

Neurotoxic event management

Parameter	N=165
Received supportive measures‡ for neurotoxic events, n (%)	14 (8.5)
Tocilizumab	3 (1.8)
Dexamethasone	3 (1.8)
Levetiracetam	2 (1.2)
Gabapentin	1 (0.6)

*This number might differ from graph values due to rounding; †TEAEs under the 'nervous system disorder' or 'psychiatric disorder' system organ class that were judged by the investigator to be related to study drug, including ICANS events; ‡Includes supportive measures to treat ICANS.

1. Moreau P, et al. *N Engl J Med* 2022;387:495–505 (and supplement); 2. Nooka A, et al. ASCO 2022. Oral presentation 8007; 3. Van de Donk NWCJ, et al. ASCO 2023. Poster 8011.

TECVAYLI®(TECLISTAMAB)THERAPY IS WELL TOLERATED AND OFFERS A PREDICTABLE AND MANAGEABLE SAFETY PROFILE

AEs reported in ≥20%, n (%)	N=165	
	Any grade	Grade 3/4
Haematological		
Neutropenia	118 (71.5)	108 (65.5)
Anaemia	90 (54.5)	62 (37.6)
Thrombocytopenia	70 (42.4)	37 (22.4)
Lymphopenia	60 (36.4)	57 (34.5)
Leukopenia	33 (20.0)	15 (9.1)
Non-haematological		
Infections	132 (80.0)	91 (55.2)
CRS	119 (72.1)	1 (0.6)
Diarrhoea	56 (33.9)	6 (3.6)
Pyrexia	52 (31.5)	1 (0.6)
Fatigue	48 (29.1)	4 (2.4)
COVID-19	48 (29.1)	35 (21.2)
Nausea	45 (27.3)	1 (0.6)
Cough	44 (26.7)	0
Injection site erythema	43 (26.1)	0
Arthralgia	42 (25.5)	1 (0.6)
Headache	40 (24.2)	1 (0.6)
Constipation	36 (21.8)	0
Hypogammaglobulinaemia	34 (20.6)	3 (1.8)

Across ~2 years of median follow-up, AEs **remained predictable and manageable**

The most common AEs remained **CRS, cytopenias and infections**

- 80.0% (132/165) of patients experienced an **infection**
- 20.6% (34/165) of patients experienced **hypogammaglobulinaemia**

Treatment discontinuations

- AEs leading to **discontinuation** were infrequent (<5%)

Deaths

- **Seven** treatment-related **deaths** occurred (four due to COVID-19)

No new safety signals were reported at ~2 years median follow-up

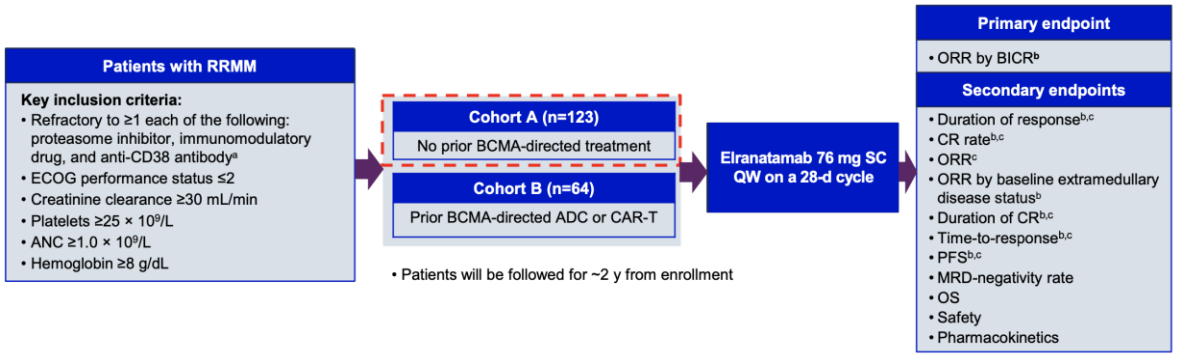
Data cut-off: 4 January 2023.[3]

1. Moreau P, et al. *N Engl J Med* 2022;387:495–505; 2. Nooka A, et al. ASCO 2022 presentation 8007; 3. Van de Donk NWCJ, et al. ASCO 2023. Poster 8011.

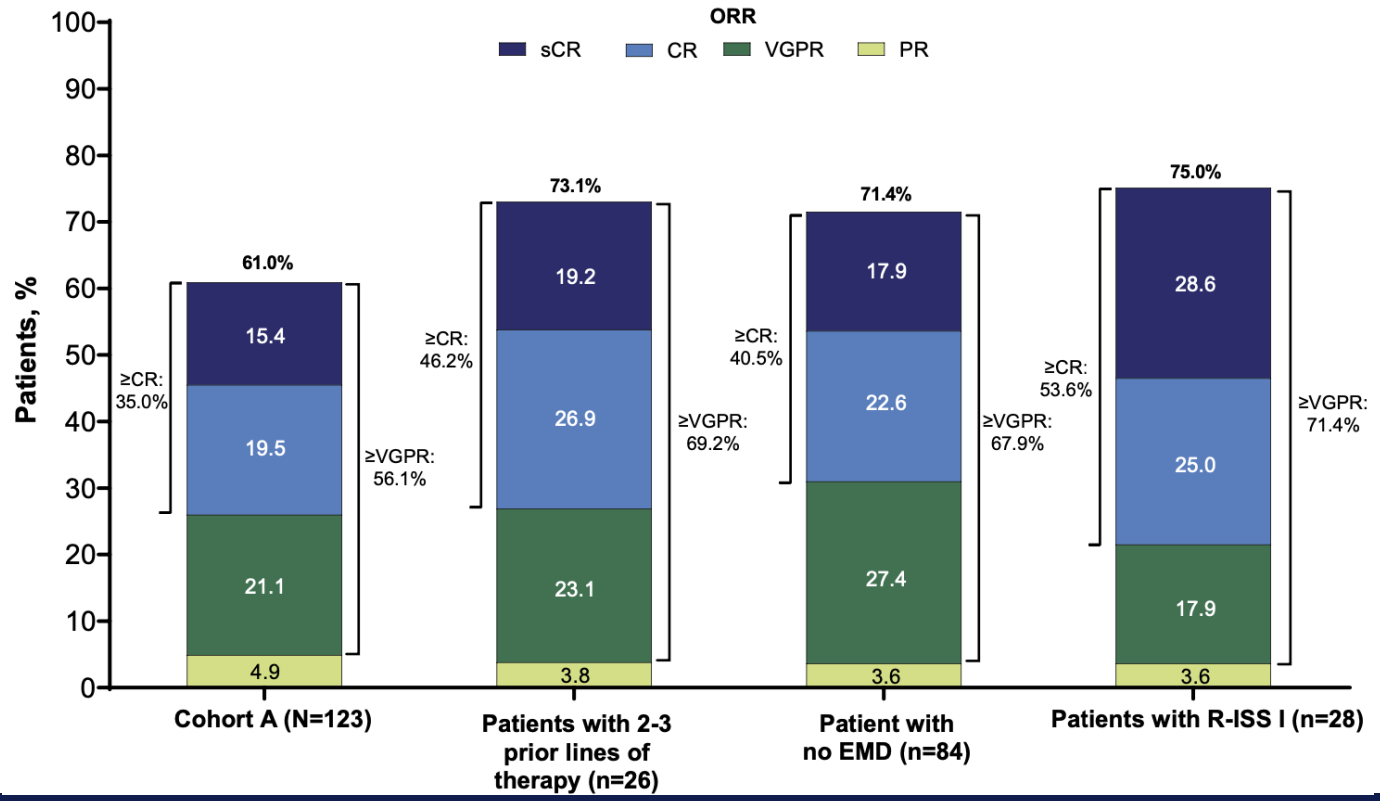
Elranatamab, a B-cell maturation antigen (BCMA)-CD3 bispecific antibody, for patients with relapsed/refractory multiple myeloma: Extended follow up and biweekly administration from MagnetisMM-3

Mohamad Mohty, MD[1], Michael H. Tomasson, MD[2], Bertrand Arnulf, MD[3], Nizar J. Bahlis, MD[4], Paula Rodríguez-Otero, MD[5], Joaquin Martinez-Lopez, MD[6], Cyrille Touzeau, MD[7], Hang Quach, MD[8], Julien Depaus, MD[9], Hisayuki Yokoyama, MD, PhD[10], Salomon Manier[11], Noopur Raje, MD[12], Marc-Steffen Raab, MD[13], Emma Searle, MD[14], Eric Leip, PhD[15], Sharon Sullivan, PhD[15], Akos Czibere, MD, PhD[16], Andrea Viqueira, MD[17], Alexander M. Lesokhin, MD[18]

EHA 2023 oral presentation S196



> 1 year follow-up



Mohty M et al. #S196 EHA 2023

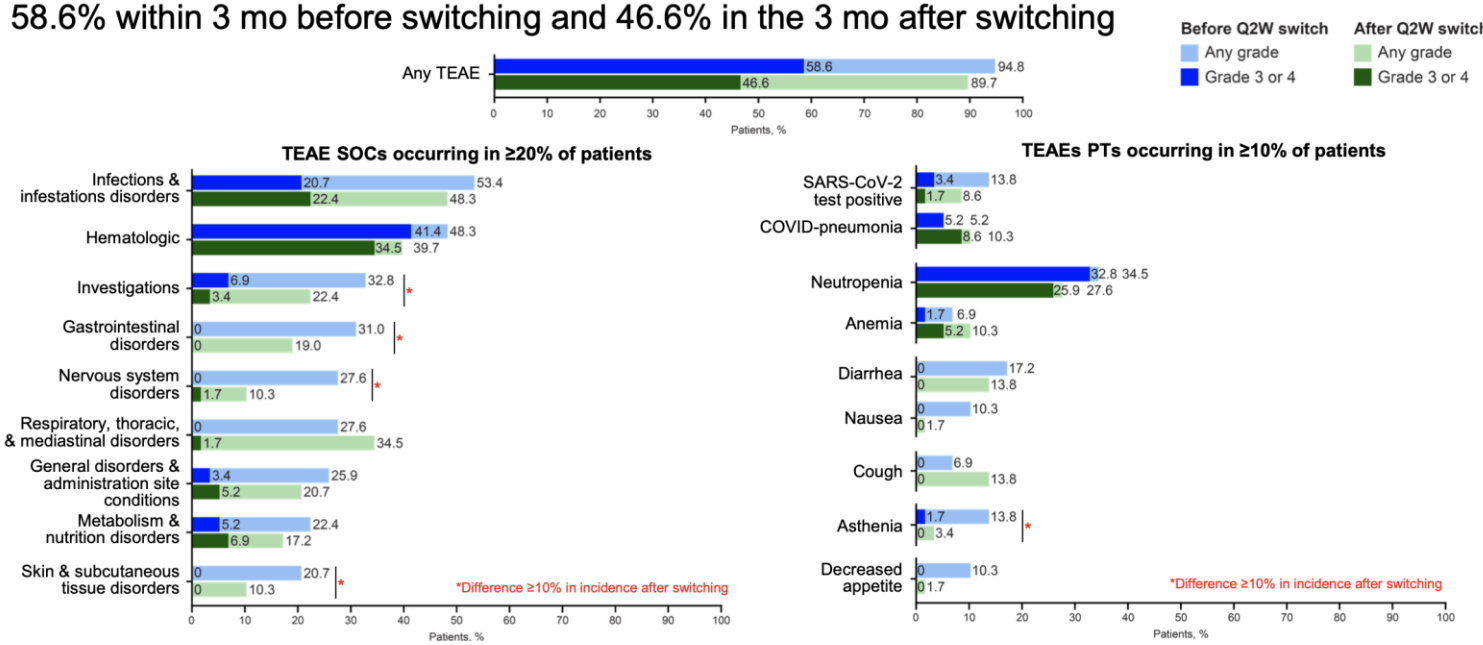
AEs of special interest – Infections:

- Infections were reported in 69.9% (grade 3/4, 39.8%; grade 5, 6.5%) of patients
- Among patients with quantitative Ig data (n=72), 98.6% had immune paresis at baseline
- Overall, 43.1% of patients received IgG replacement during the study

Patients, n (%)	Cohort A (N=123)		
	Any grade	Grade 3/4	Grade 5
Infection TEAEs in ≥5% of patients			
COVID-19–related[a]	36 (29.3)	19 (15.4)	2 (1.6)
Upper respiratory tract infection	20 (16.3)	0	0
Pneumonia	20 (16.3)	10 (8.1)	0
Sinusitis	13 (10.6)	2 (1.6)	0
Urinary tract infection	12 (9.8)	4 (3.3)	0
Sepsis	8 (6.5)	8 (6.5)	0
Bacteremia	7 (5.7)	2 (1.6)	0
CMV reactivation	7 (5.7)	2 (1.6)	0
Key infections occurring in <5% of patients[b]			
Pneumocystis jirovecii pneumonia	6 (4.9)	5 (4.1)	0
CMV infection	4 (3.3)	0	0
Adenoviral hepatitis	1 (0.8)	0	1 (0.8)
Adenovirus infection	1 (0.8)[c]	0	1 (0.8)[c]
Hepatitis B reactivation	1 (0.8)	0	0
Pneumonia adenoviral	1 (0.8)[c]	0	1 (0.8)[c]
Pneumonia cytomegaloviral	1 (0.8)	1 (0.8)	0
Pneumonia pseudomonal	1 (0.8)	0	1 (0.8)

Safety with Q2W dosing

Incidence of grade 3/4 TEAEs decreased by >10% after **switching to Q2W dosing**; 58.6% within 3 mo before switching and 46.6% in the 3 mo after switching



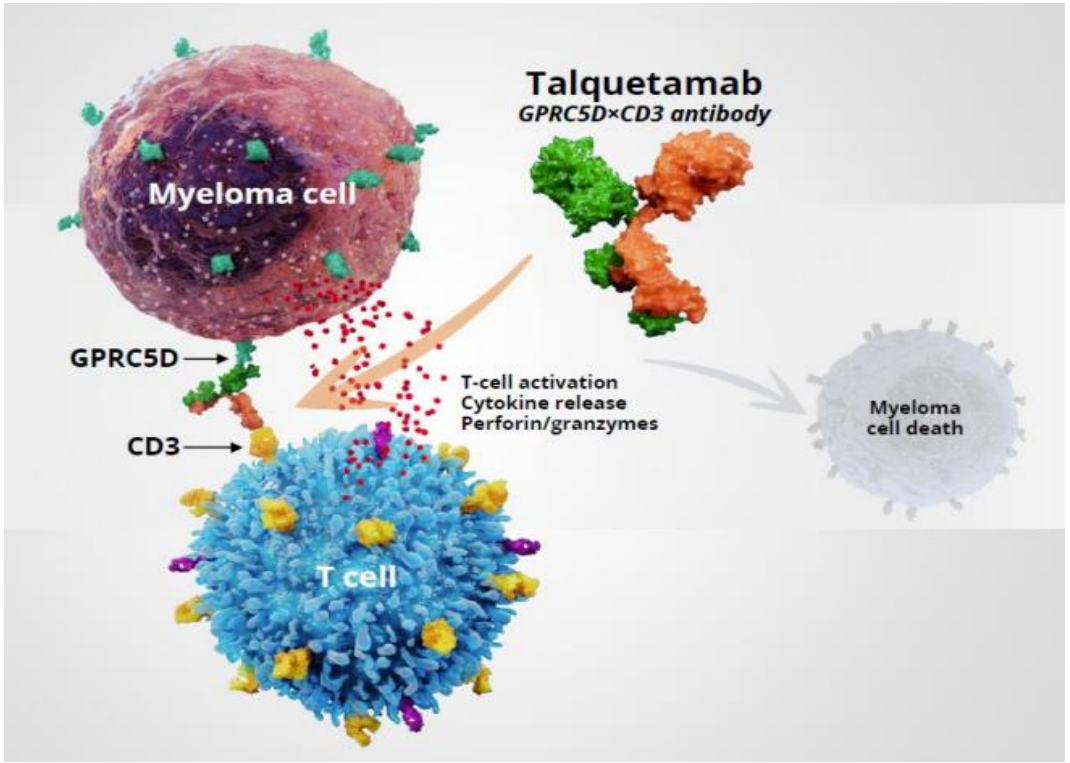
Mohty M et al. #S196 EHA 2023

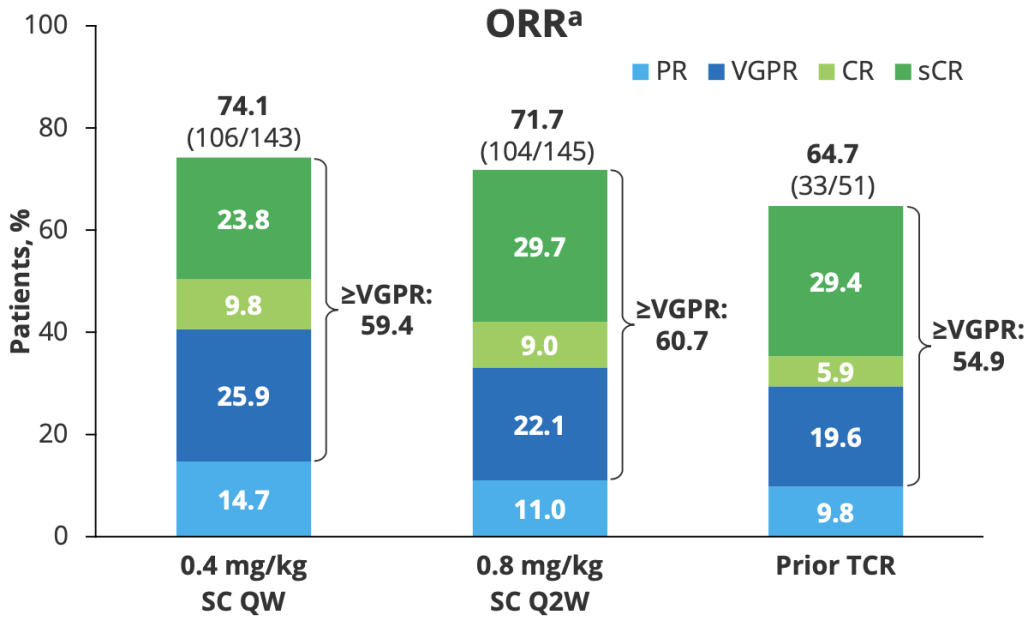
TALVEY® (Talquetamab) is a 'First-in-class' T-Cell redirector with a novel distinct target

Talquetamab is a new immunotherapy: a first-in-class T-cell redirector with a novel, distinct target and a new mechanism of action

- Talquetamab can be sequenced pre- or post-BCMA

Talquetamab is a **first-in-class**, off-the-shelf BsAb targeting GPRC5D, a **novel antigen overexpressed** on malignant plasma cells



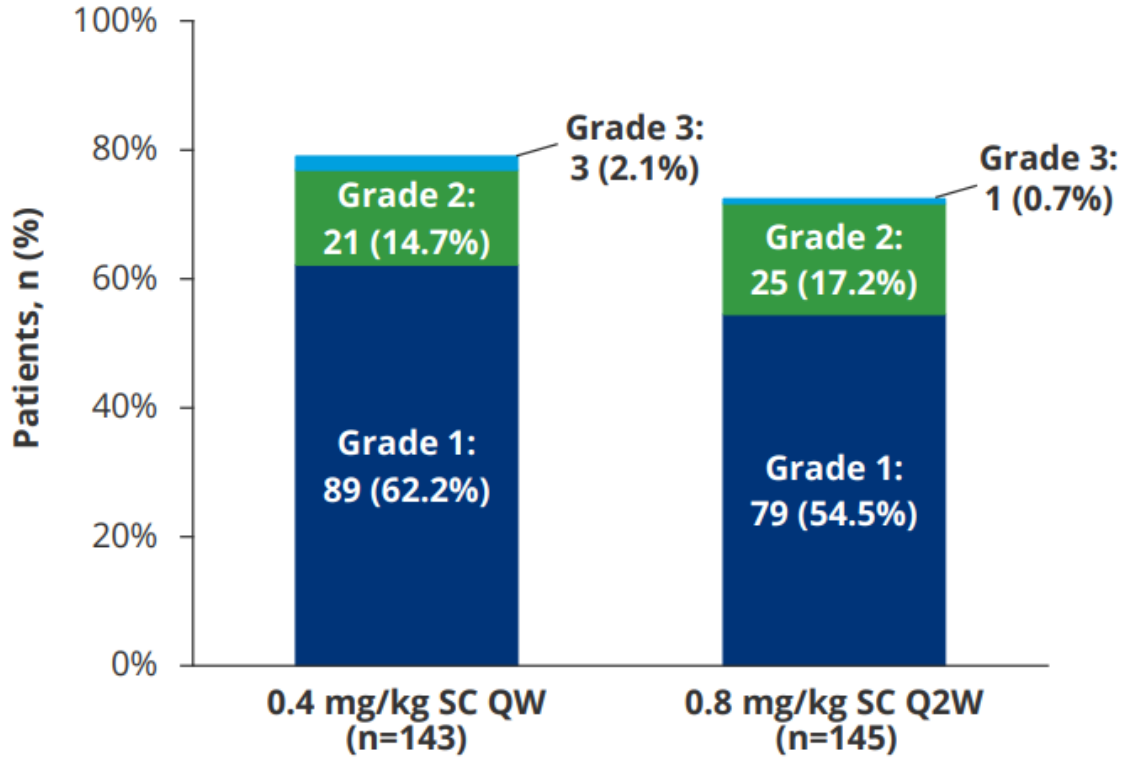


Tozeau C et al. #S191 EHA 2023

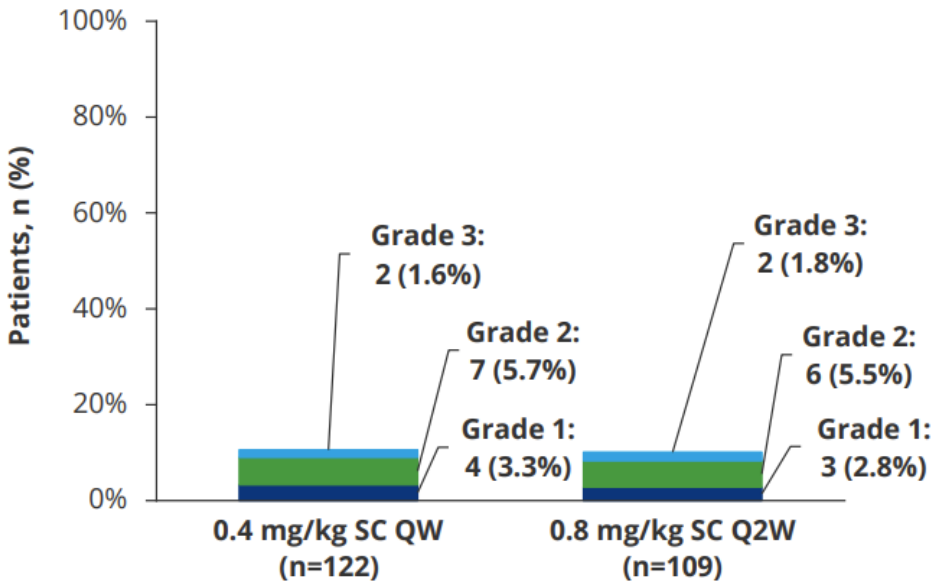
TALVEY® (Talquetamab) has a manageable safety profile

CRS rates and severity are in line with reported incidence for bispecifics

Maximum CRS Grade

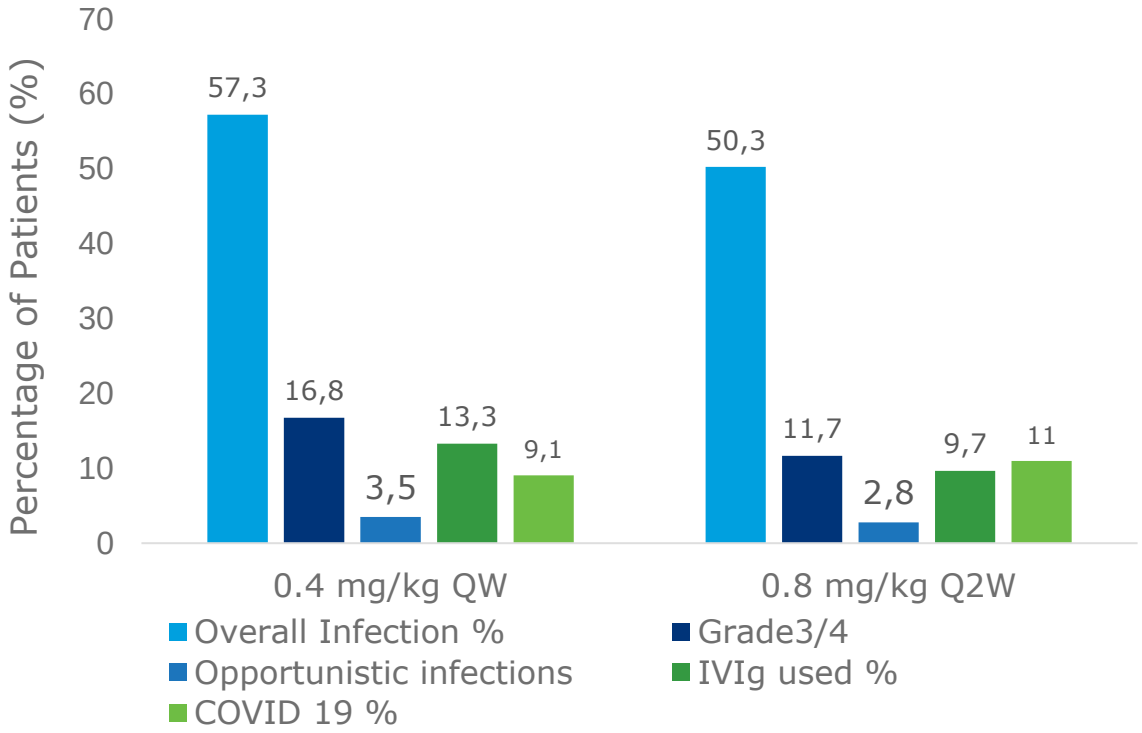


Maximum ICANS Grade



1. Touzeau C, et al. EHA 2023, Oral S191*;* 2. Chari A, et al. ASH 2022, Oral P157;3. Rasche L, et al. EHA 2023, Poster P892; 4. TALVEY® Fachinformation 08/2023; 5. Martin G, et al. Cancer 2023

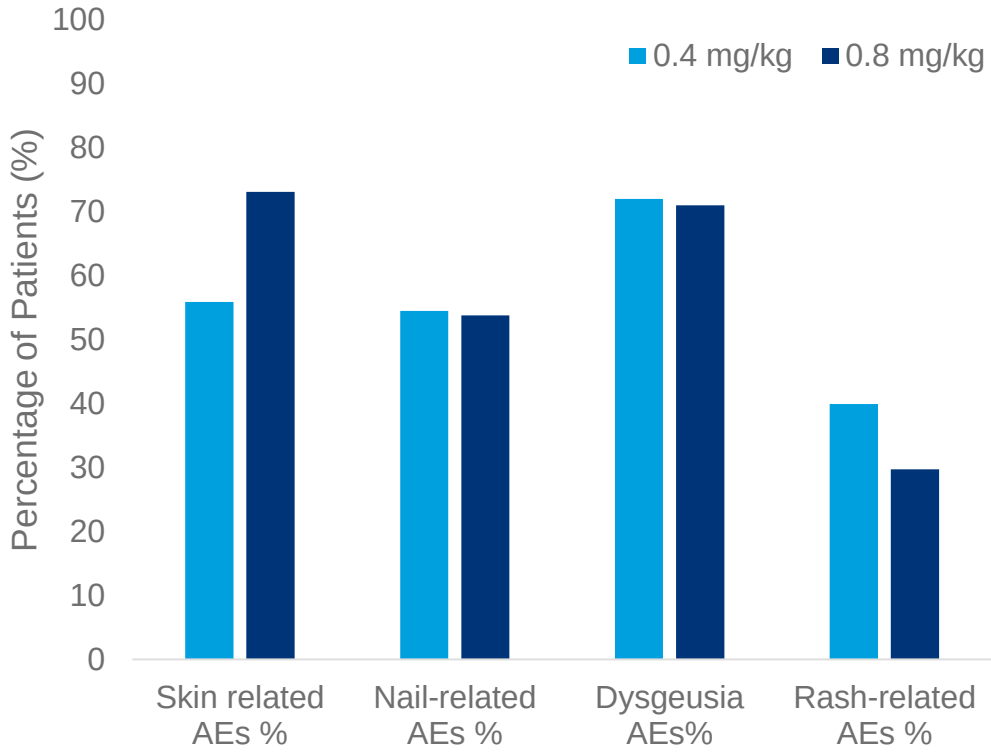
Talquetamab Side effects



~20% of patients experienced grade 3/4 infections, with low rates of opportunistic infections, discontinuations and deaths due to infections

relatively low grade3/4 infections …

Oral-, skin-, and nail-related AEs were not treatment limiting



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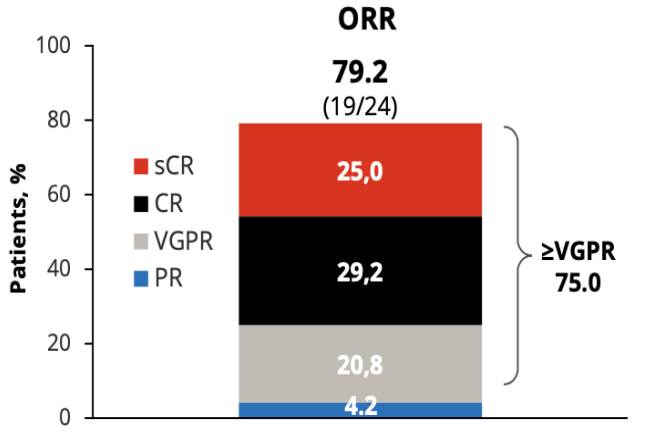
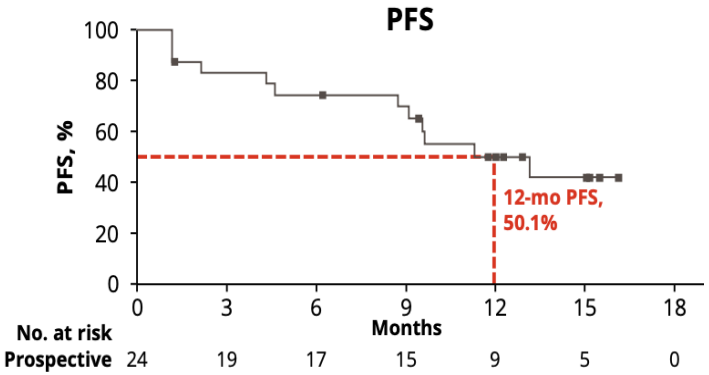
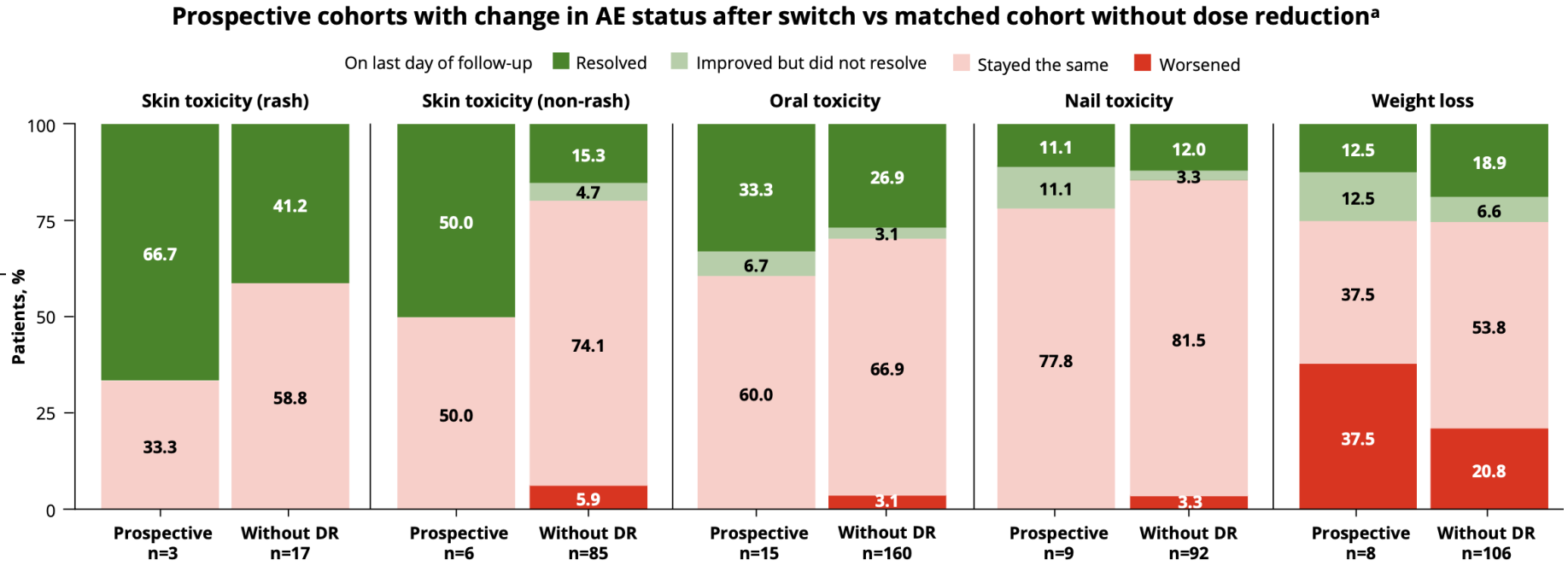






- Trend toward improved resolution of GPRC5D-related AEs, except weight loss

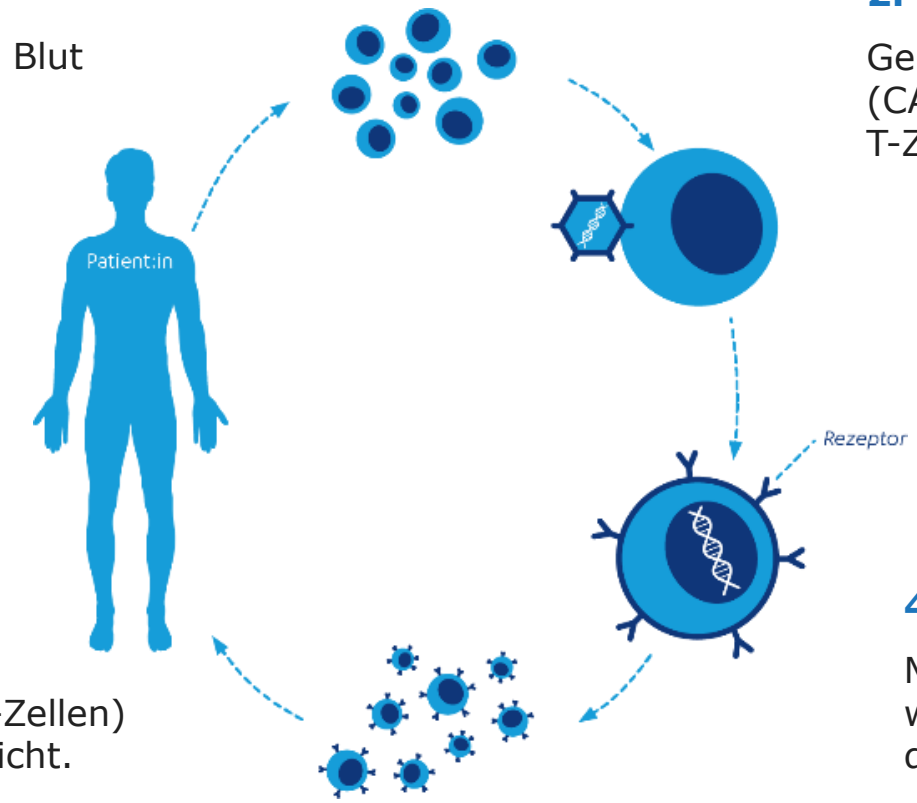
Chiari A et al, oral presentation #1010, **ASH 2023**

CARTs
(targeting BCMA)

Grundprinzip der CAR-T-Zelltherapie

1. Leukapherese:

Leukozyten werden aus dem Blut der Patient:innen isoliert.



2. Transduktion:

Gene für chimäre Antigenrezeptoren (CAR) werden viral in isolierte T-Zellen eingebracht.

3. Expression:

T-Zellen können nun funktionale CARs auf ihrer Oberfläche exprimieren.

4. Expansion:

Modifizierte T-Zellen werden vermehrt und für die Infusion vorbereitet.

5. Infusion:

Aufbereitete und modifizierte T-Zellen (CAR-T-Zellen) werden per Infusion verabreicht.

CAR: Chimärer Antigenrezeptor

Rezente Zulassungserweiterungen:

ABECMA®
Idecabtagene vicleucel
RRMM nach ≥ 3 Therapien inkl. PI, IMiD, CD38 Ab

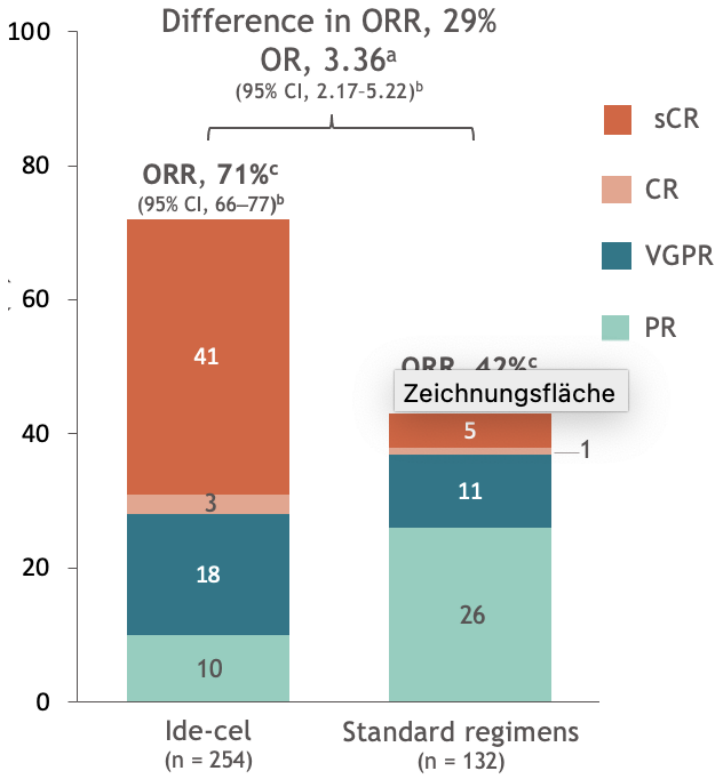
≥ 2 Therapien inkl. Dara, PI und IMiD, Progress auf letzte Therapie

CARVYKTI®
Ciltacabtagene autoleucel
RRMM nach ≥ 3 Therapien inkl. PI, IMiD, CD38 Ab

≥ 1 Therapie inkl. PI und IMiD, Len-refraktär und Progress auf letzte Therapie

Idecabtagene vicleucel versus standard regimens in patients with triple-class–exposed relapsed and refractory multiple myeloma: updated analysis from KarMMa-3

Paula Rodríguez-Otero,[1] Sikander Ailawadhi,[2] Bertrand Arnulf,[3] Krina K. Patel,[4] Michele Cavo,[5] Ajay K. Nooka,[6] Salomon Manier,[7] Natalie Callander,[8] Luciano J. Costa,[9] Ravi Vij,[10] Nizar J. Bahlis,[11] Philippe Moreau,[12] Scott Solomon,[13] Ingerid Weum Abrahamsen,[14] Rachid Baz,[15] Annemiek Broijl,[16] Christine Chen,[17] Sundar Jagannath,[18] Noopur Raje,[19] Christof Scheid,[20] Michel Delforge,[21] Reuben Benjamin,[22] Thomas Pabst,[23] Shinsuke Iida,[24] Jesus Berdeja,[25] Anna Truppel-Hartmann,[26] Rashmi Bhatnagar,[27] Fan Wu,[28] Julia Piasecki,[28] Laurie Eliason,[28] Devender Dhanda,[28] Jasper Felten,[29] Andrea Caia,[29] Mark Cook,[29] Mihaela Popa McKiver,[28] Sergio Giralt[30]



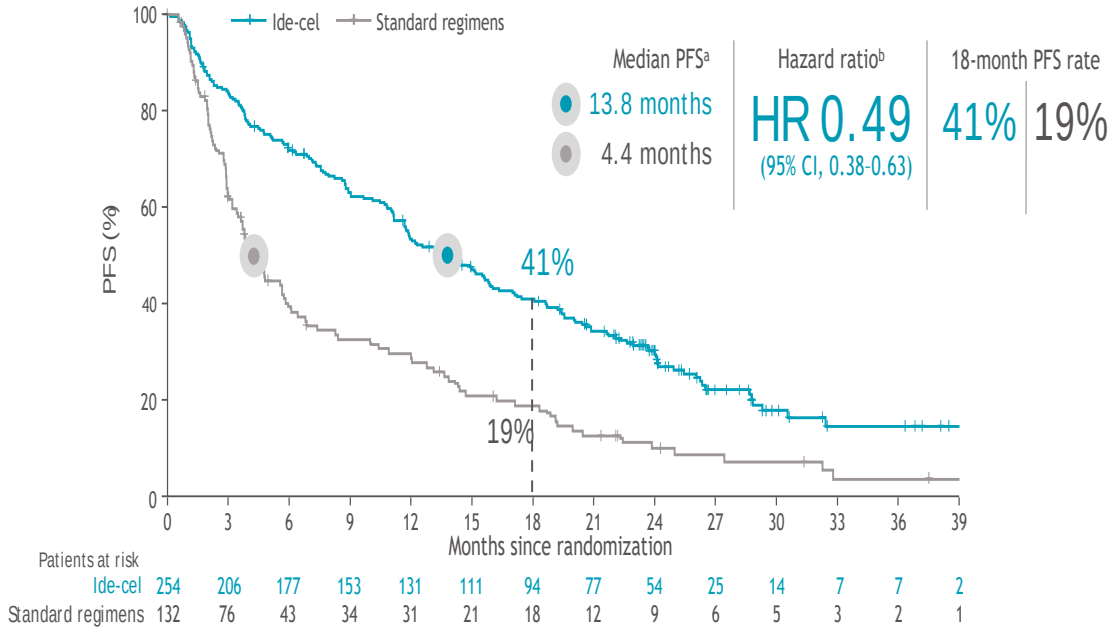
Secondary endpoint	Ide-cel (n = 254)	Standard regimens (n = 132)
CR rate (95 % CI), %[d]	44 (38-50)	5 (2-9)
MRD-negative CR rate, n/N (%) (95% CI)[e]	57/163 (35) (28-42)	1/54 (2) (0-5)
Median (95% CI) DOR, months	16.6 (12.1-19.6)	9.7 (5.5-16.1)
Median PFS2, months	23.5	16.7
HR (95% CI)	0.79 (0.60-1.04)	

Treated population, n (%)	Ide-cel (n = 225)
CRS[b]	
Any grade	197 (88)
Grade 3/4	9 (4)
iiNT[c]	
Any grade	34 (15)
Grade 3/4	7 (3)
Infections	
Any grade	125 (56)
Grade 3/4	50 (22)

Rodriguez-Otero P et al, oral presentation #1028, ASH 2023

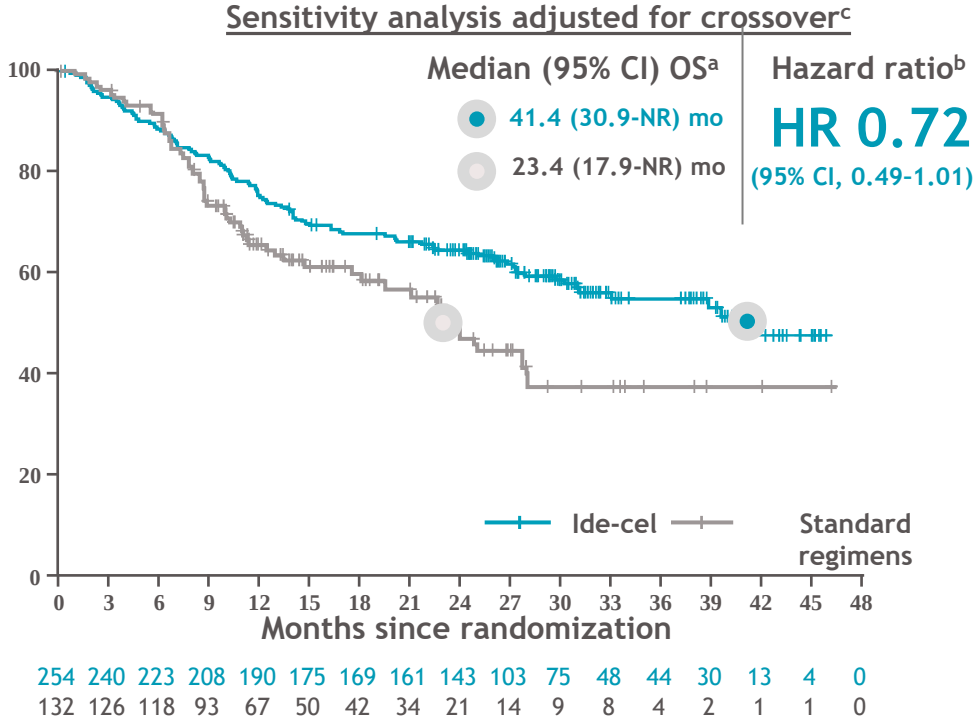
Keine Langzeit-Toxizitäten i.S. Parkinsonismus oder Guillain/Barre´
No SPMs of T-cell origin

Ide-cel versus standard of care regimens in patients with triple class-exposed RRMM: Updated analysis of the KarMMa-3 study



SoC were Kd, EloPd, DPd, Ird and DVd

- ORR was 71% in ide-cel vs 42% in SoC
- sCR/CR was 44% in ide-cel vs 6% in SoC
- MRD-ve CR rate was 35% vs 2%

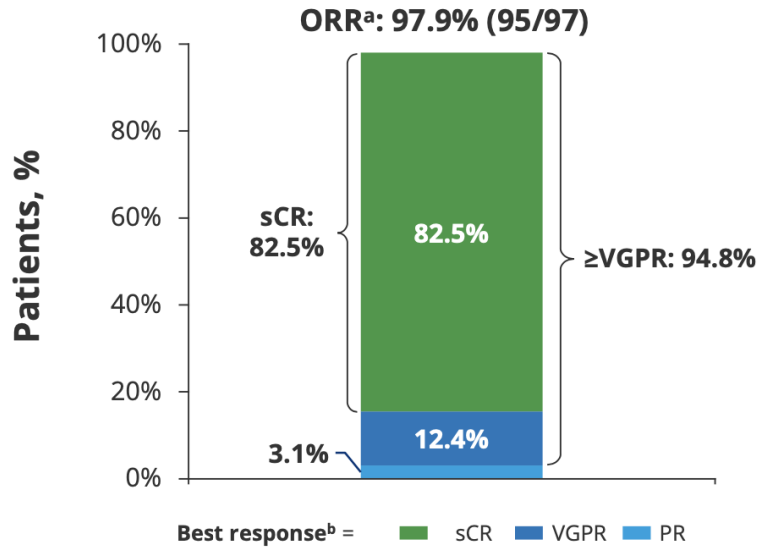


Rodriguez-Otero P, et al. **ASH 2023** (Abstract No. 1028 – oral presentation).

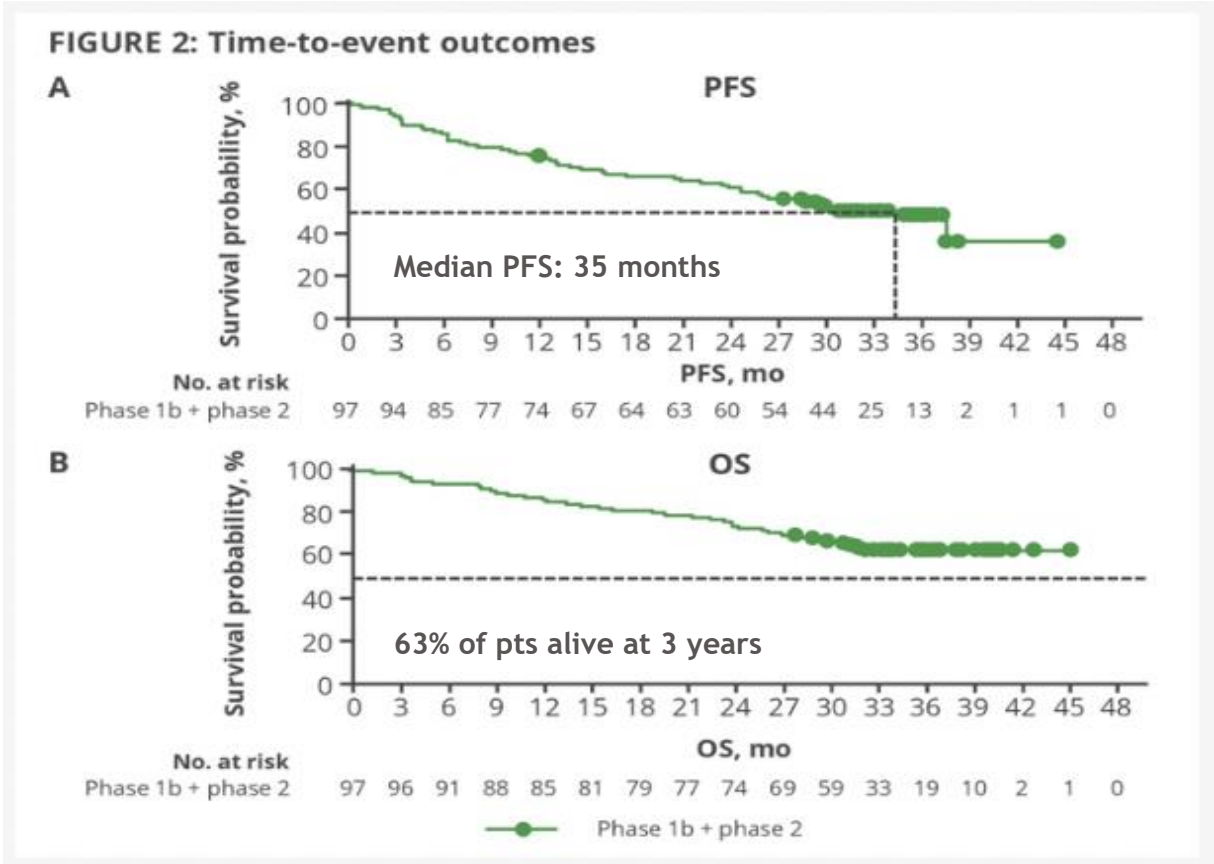
CARTITUDE-1 Final Results: Phase 1b/2 Study of Ciltacabtagene Autoleucel in Heavily Pretreated Patients With Relapsed/Refractory Multiple Myeloma

Yi Lin[1], Thomas G Martin[2], Saad Z Usmani[3], Jesus G Berdeja[4], Andrzej J Jakubowiak[5], Mounzer E Agha[6], Adam D Cohen[7], Abhinav Deol[8], Myo Htut[9], Alexander M Lesokhin[3], Nikhil C Munshi[10], Elizabeth O'Donnell[11], Carolyn C Jackson[12], Tzu-Min Yeh[12], Arnob Banerjee[13], Enrique Zudaire[13], Deepu Madduri[12], Christopher delCorral[14], Lida Pacaud[14], Sundar Jagannath[15]

CARTITUDE-1 Final Results: Study Population
(~3-Year Follow-Up)



Munshi N et al. #S202 EHA 2023



Safety profile:

No new neurotoxic events;

FDA warning about T- cell malignancies and SPM in general[2]

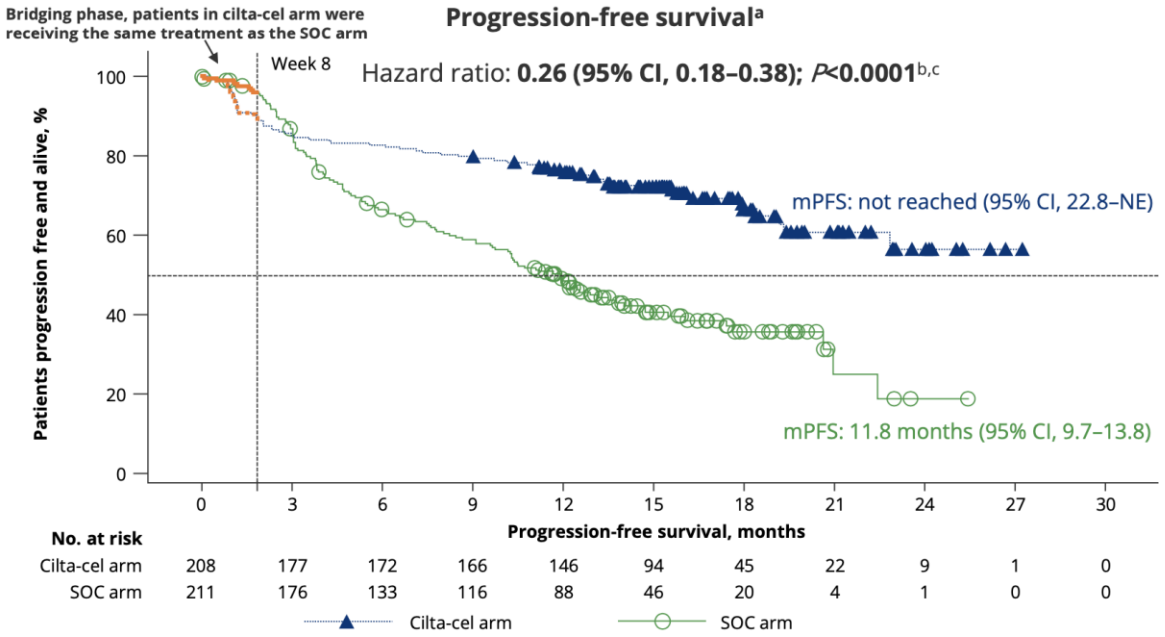
26 SPM reported throughout the study in 20 patients including 7 MDS, 1 B-cell NHL and 3 AML

T-cell malignancies: 1 case reported with cilta-cel[3]

1. Lin Y, et al. ASCO 2023 (Abstract No. 8009 – oral presentation); 2. Press release. Available at: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-investigating-serious-risk-t-cell-malignancy-following-bcma-directed-or-cd19-directed-autologous (last accessed January 2024);
3. Harrison SJ, et al. Blood 2023;142(Supplement 1):6939.

Phase 3 Results From CARTITUDE-4: Cilta-cel Versus Standard of Care (PVd or DPd) in Lenalidomide-Refractory Multiple Myeloma

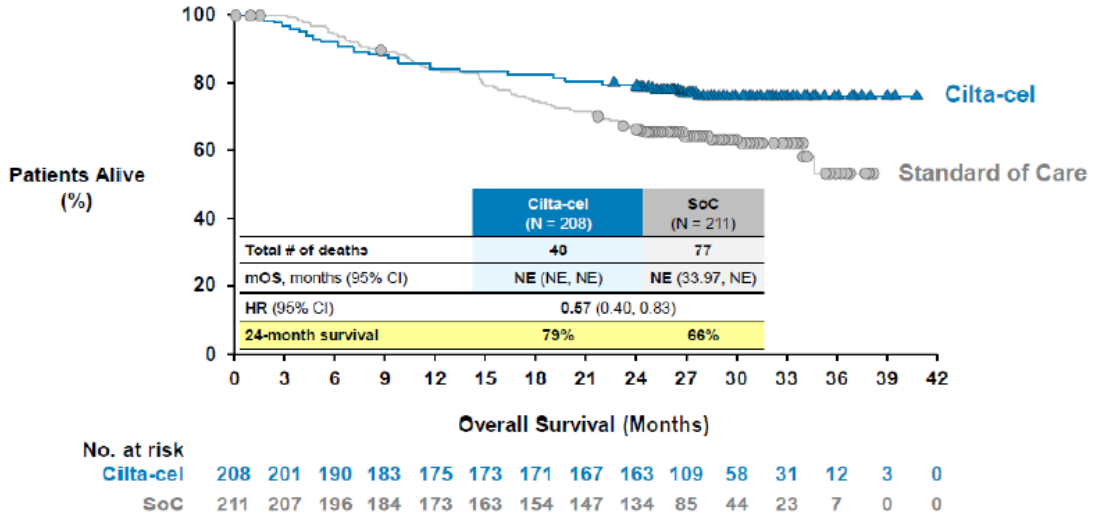
Binod Dhakal[1], Kwee Yong[2], Simon Harrison[3], María-Victoria Mateos[4], Philippe Moreau[5], Niels WCJ van de Donk[6], Surbhi Sidana[7], Rakesh Popat[8], Nikoletta Lendvai[9], Carolina Lonardi[10], Ana Slaughter[11], Jordan M Schecter[9], Katherine Li[12], Enrique Zudaire[12], Diana Chen[13], Jane Gilbert[14], Lida Pacaud[15], Nitin Patel[15], Jesús San-Miguel[16], Hermann Einsele[17]



Cilta-cel vs SOC

- 12-month PFS rate: 76% vs 49%
- SOC performed as expected

Figure 7: CARTITUDE-4 Study: Kaplan-Meier Plot for Overall Survival (ITT Analysis Set; 13 December 2023 Survival Sweep)



ITT=Intent-to-Treat; mOS=median overall survival; NE=not estimable; SoC=standard of care.

Dakhal B, et al. **ASCO 2023** (Abstract No. LBA106 – oral presentation).

Wichtig zu wissen **VOR** CART-Zelltherapie: Optimierung des klinischen Outcomes

Patientenselektion für eine CAR-T Zell-Therapie beim Multiplen Myelom

Auswahlkriterien

- Erhaltene Organfunktionen (EF > 45%, NYHA < 2, SpO_2 > 91%, LFP < 2,5 ULN, eGFR >30 ml/min*)
- Keine schwere Zytopenie (ANC > 1,0 G/l, PLT > 50 G/l, Hb > 8 g/dl)
- Keine aktive ZNS-Beteiligung oder neurolog. Erkrankung
- ECOG ≤ 2*

Risikofaktoren für kürzeres/schlechteres Ansprechen

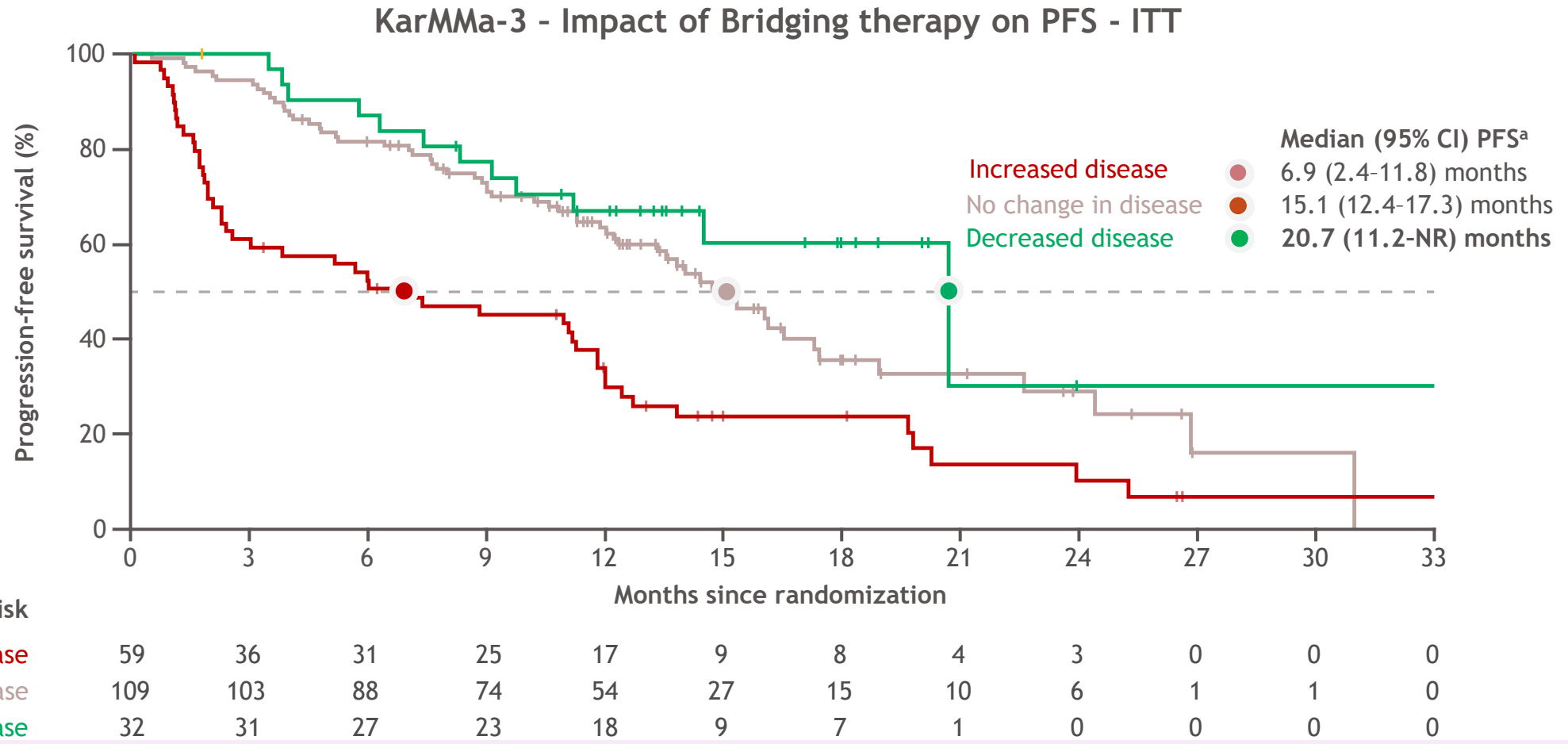
- ISS III
- High-Risk Zytogenetik
- Hohe Tumormasse
- EMD (paraskelettal ≠ Weichteil)
- ⇧ inflammatorische Biomarker vor CAR-T
- „Exhausted“ T-Zell-Profil (⇧ CD4+ Treg cell like phenotype, ⇩ CD8+ stem-cell like phenotype)

Risikofaktoren für erhöhtes Komplikationsrisiko

- Hohe Tumormasse
- CRS ≥ Grad 2
- ICANS
- Neurolog. Vorerkrankung
- ⇧ inflammatorische Biomarker vor CAR-T
- Schwere Zytopenien vor CAR-T
- ⇧ CAR-T Peak Expansion

*basierend auf MM Real World Daten, entspricht nicht den aktuellen CAR-T Plattform Kriterien; Hansen DK et al, JCO 2023; Hansen DK et al, #8012, ASCO 2023 Greinix H et al, memo 2020; Martin T et al, JCO 2023; Montes de Oca R et al, #2099 ASH 2023; Cohen AD et al, Blood Cancer J 2022; Rejeski K et al, J Hematol Oncol 2023

Debulking of the disease burden leads to prolonged PFS



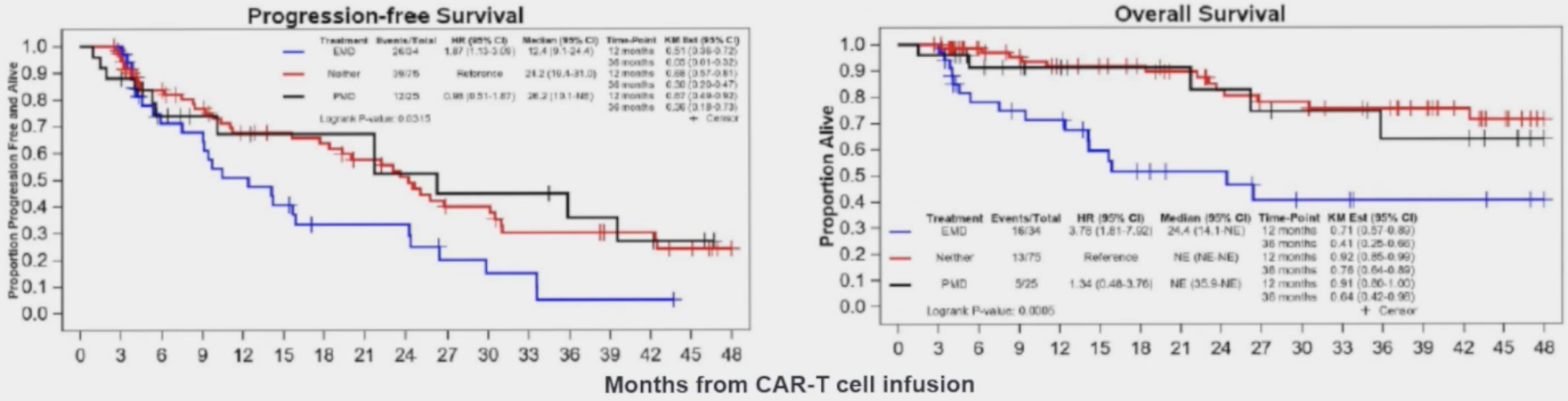
Ide-cel combined with effective bridging strategy can be associated with more durable PFS

PFS per IRC based on IMWG criteria according to FDA censoring rules. [a]Median and 95% CI are based on Kaplan-Meier approach.
Einsele, et al. IMS 2023. [Poster P-008]

Extramedulläre Erkrankung …

- 4/2017 – 2/2023; n=134; mFU: 19 Monate; n=59 Ciltacel; n=52 Idecel; n=23 sonstige;
- Bei 28/34 EMD-Rezidiv wurde KM auf MRD untersucht, davon 43% MRD- in next-generation-flow (10-5)
- EMD post-BCMA CAR T wurde in n=7 biopsiert und gefärbt, davon n=6 BCMA+

	EMD+ (%)	PMD+ (%)	EMD-, PMD-
PFS	**HR 1,87**, 95% KI 1,13-3,09	HR 0,98, 95% CI 0,51-1,87	1,0
OS	**HR 3,78**, 95% KI 1,81-7,92	HR 1,34, 95% CI 0,48-3,76	1,0
ORR (%)	77 (57 für SPD ≥50cm² (n=7), davon 3 PD, 3 PR, 1 VGPR) (82 für SPD <50cm² (n=27), davon 18 CR)	92	88



- EMD (Ø PMD): sig. schlechteres PFS + OS post-CAR-Ts; EMD+ SPD <50cm² zeigt besseres Ansprechen
- Mehrheit mit Baseline-EMD erlitt Rezidiv trotz radiografisch post-CAR T EMD-; 43% der EMD-Rezidive post-CAR T blieben MRD- im KM
- EMD-Kontrolle vor CAR-Ts mit optimalem Bridging u/od. Radiatio
- KM-MRD allein: Ø gutes Maß für Gesamterkrankungskontrolle post-CAR T

Pan D et al, oral presentation #1006, **ASH 2023**

Vielen Dank für Ihre Aufmerksamkeit!