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Lymphomen & Leukämien

Kompetenznetz
Maligne Lymphome

EHA2023 HYBRID

Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

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Expert:innen berichten zu Lymphomen & Leukämien

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Multiples Myelom (MM)

EHA2023 HYBRID

Offenlegung potentieller Interessenskonflikte

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Finanzierung wissenschaftlicher Untersuchungen	Abbvie, Amgen, Bristol Myers Squibb/Celgene, GSK, Janssen, Sanofi (Institution)
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Immaterielle Interessenkonflikte	

Kapitel 1

Wird die CAR-T Zelltherapie der neue Behandlungsstandard?

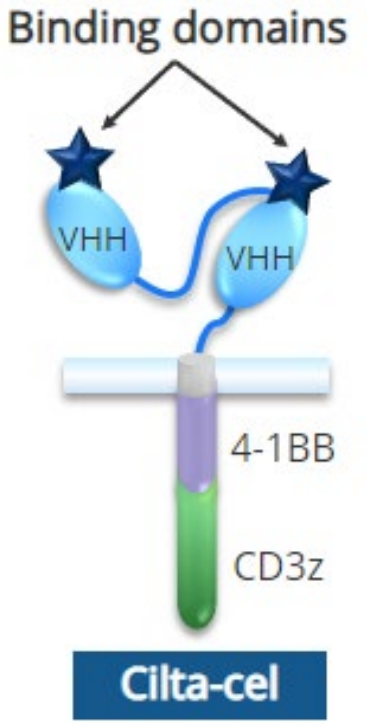
Cilta-Cel im 1.-3. Rezidiv

S100: FIRST PHASE 3 RESULTS FROM CARTITUDE-4: CILTA-CEL VERSUS STANDARD OF CARE (PVD OR DPD) IN LENALIDOMIDE-REFRACTORY MULTIPLE MYELOMA

Hermann Einsele, Kwee Yong, Simon Harrison, Maria-Victoria Mateos, Philippe Moreau, Niels W.C.J. van de Donk, Surbhi Sidana, Rakesh Popat, Nikoletta Lendvai, Carolina Lonardi, Ana Slaughter, Jordan Schecter, Katherine Li, Enrique Zudaire, Diana Chen, Jane Gilbert, Tzu-Min Yeh, Lida Pacaud, Nitin Patel, Binod Dhakal, Jesús San Miguel

Cilta-Cel im 1.-3. Rezidiv

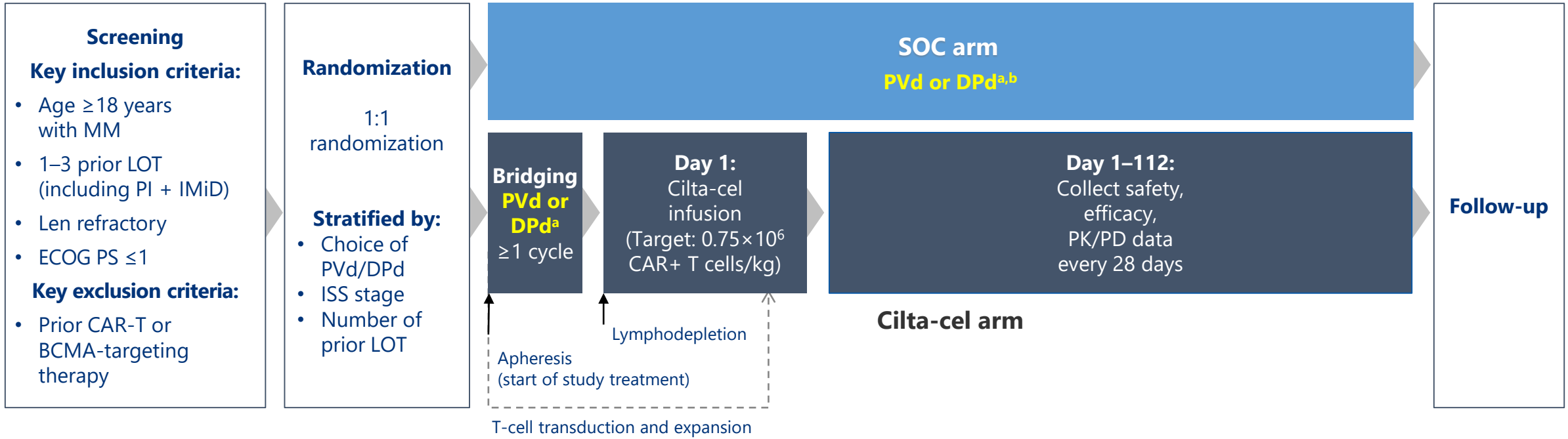
S100: FIRST PHASE 3 RESULTS FROM CARTITUDE-4: CILTA-CEL VERSUS STANDARD OF CARE (PVD OR DPD) IN LENALIDOMIDE-REFRACTORY MULTIPLE MYELOMA



- Cilta-cel is a **dual-binding**, BCMA-directed CAR-T therapy
- The phase 1b/2 **CARTITUDE-1** study has shown a median PFS of ~3 years **in heavily pretreated** patients with MM with ≥3 prior LOT
- We aimed to test cilta-cel in **earlier lines** against effective SOC treatments
  - In real-world studies, patients with lenalidomide-refractory disease often have median PFS <12 months[1]
- **The phase 3 CARTITUDE-4 study compared cilta-cel vs physician's choice of either DPd or PVd in patients with lenalidomide-refractory MM after 1–3 prior LOT[2]**
  - This represents a patient population with clear unmet need commonly seen in clinical practice
  - Median follow-up was 15.9 months

Cilta-Cel im 1.-3. Rezidiv

S100: FIRST PHASE 3 RESULTS FROM CARTITUDE-4: CILTA-CEL VERSUS STANDARD OF CARE (PVD OR DPD) IN LENALIDOMIDE-REFRACTORY MULTIPLE MYELOMA



- Primary endpoint
  - PFS[c]
- Secondary endpoints
  - Efficacy: ≥CR, ORR, MRD negativity, OS
  - Safety
  - PROs

Cilta-Cel im 1.-3. Rezidiv

S100: FIRST PHASE 3 RESULTS FROM CARTITUDE-4: CILTA-CEL VERSUS STANDARD OF CARE (PVD OR DPD) IN LENALIDOMIDE-REFRACTORY MULTIPLE MYELOMA

Baseline characteristic	ITT population	
	Cilta-cel (n=208)	SOC (n=211)
Age, median (range), years	61.5 (27–78)	61.0 (35–80)
Male, n (%)	116 (55.8)	124 (58.8)
White, n (%)	157 (75.5)	157 (74.4)
ECOG PS ≤1, n (%) [a,b]	207 (99.5)	210 (99.5)
ISS stage, n (%)		
I	136 (65.4)	132 (62.6)
II	60 (28.8)	65 (30.8)
III	12 (5.8)	14 (6.6)
Bone marrow plasma cells ≥60%,[c] n (%)	42 (20.4)	43 (20.7)
Presence of soft tissue plasmacytomas,[d] n (%)	44 (21.2)	35 (16.6)
Years since diagnosis, median (range)	3 (0.3–18.1)	3.4 (0.4–22.1)
Prior LOT, median (range)	2 (1–3)	2 (1–3)
1 prior LOT, n (%)	68 (32.7)	68 (32.2)
2 or 3 prior LOT, n (%)	140 (67.3)	143 (67.8)

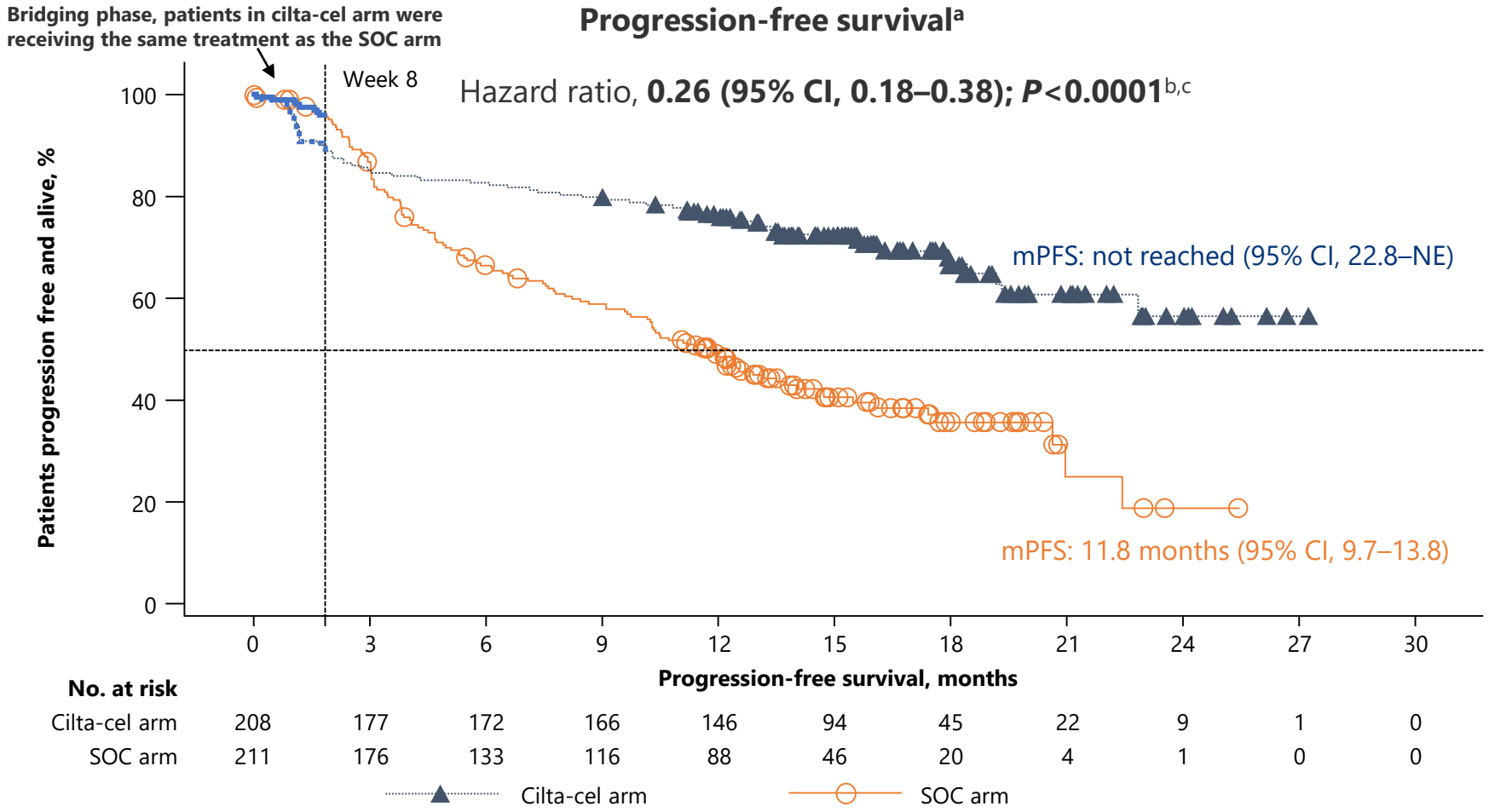
Baseline characteristic	ITT population	
	Cilta-cel (n=208)	SOC (n=211)
Cytogenetic high risk, n (%)[e]	123 (59.4)	132 (62.9)
del(17p)	49 (23.7)	43 (20.5)
t(14;16)	3 (1.4)	7 (3.3)
t(4;14)	30 (14.5)	30 (14.3)
gain/amp(1q)	89 (43.0)	107 (51.0)
2 or more high-risk cytogenetic features	43 (20.8)	49 (23.3)
del(17p), t(14;16), or t(4;14)	73 (35.3)	69 (32.9)
Triple-class[f] exposed, n (%)	53 (25.5)	55 (26.1)
Penta-drug[g] exposed, n (%)	14 (6.7)	10 (4.7)
Refractory status, n (%)		
Triple-class refractory[f,h]	30 (14.4)	33 (15.6)
Bortezomib	55 (26.4)	48 (22.7)
Pomalidomide	8 (3.8)	9 (4.3)
Daratumumab	48 (23.1)	45 (21.3)
Any PI	103 (49.5)	96 (45.5)

Cilta-Cel im 1.-3. Rezidiv

S100: FIRST PHASE 3 RESULTS FROM CARTITUDE-4: CILTA-CEL VERSUS STANDARD OF CARE (PVD OR DPD) IN LENALIDOMIDE-REFRACTORY MULTIPLE MYELOMA

Cilta-cel vs SOC

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



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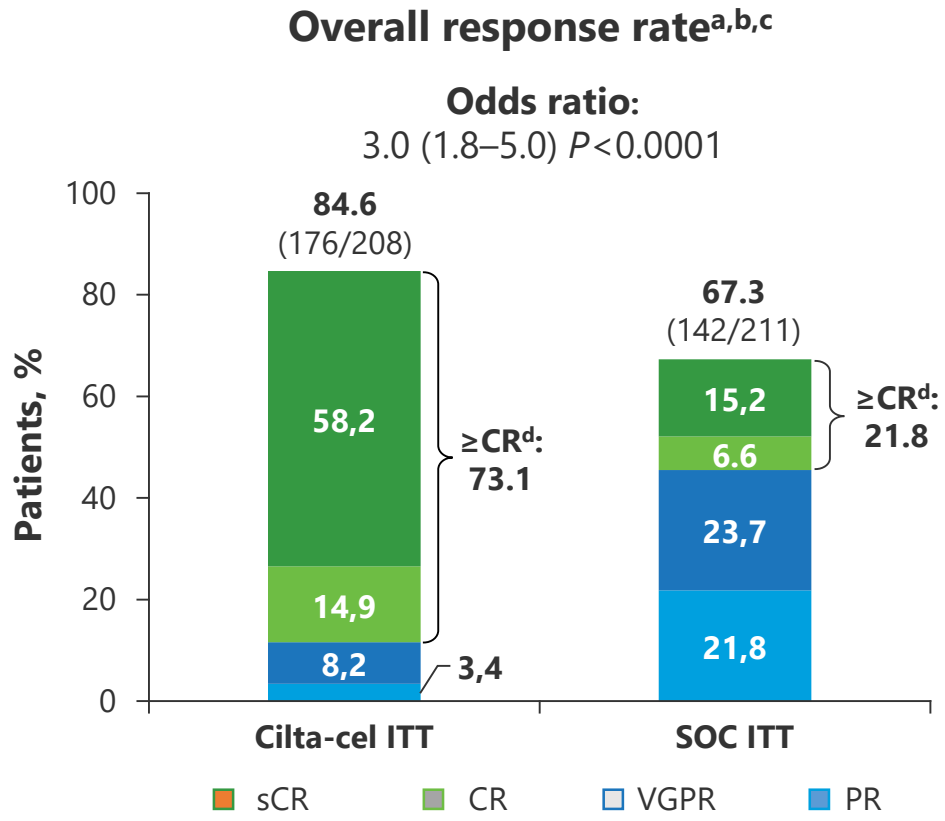
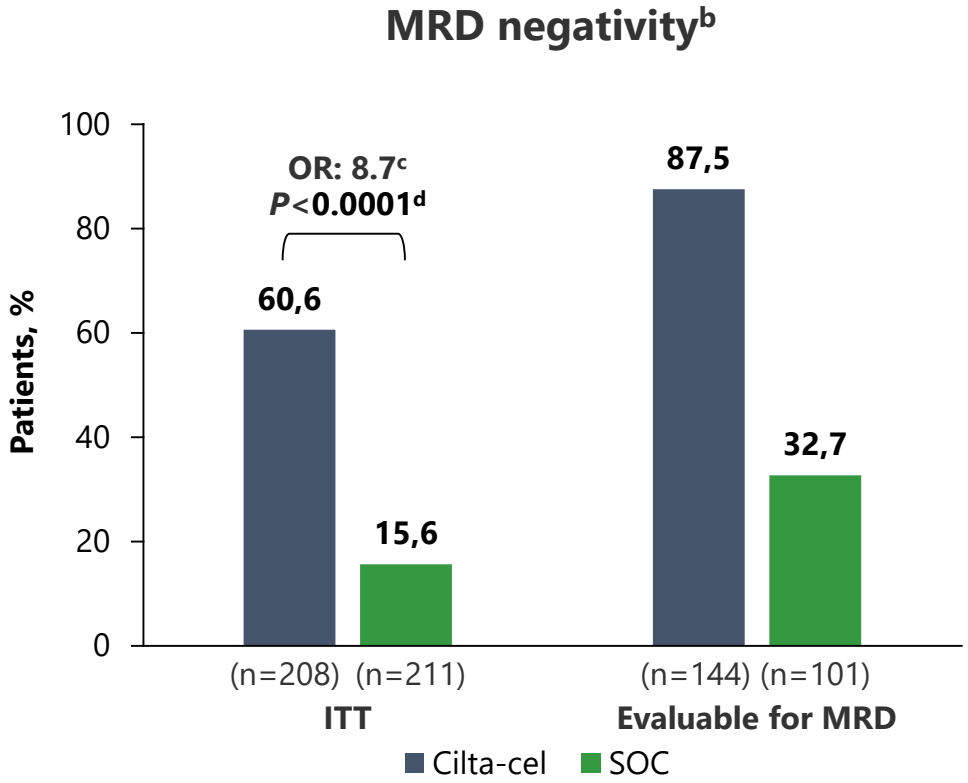
- Cilta-cel had higher ORR vs SOC



- Cilta-cel improved rates of overall MRD negativity[a,b] at 10^{-5} vs SOC



Cilta-Cel im 1.-3. Rezidiv

S100: FIRST PHASE 3 RESULTS FROM CARTITUDE-4: CILTA-CEL VERSUS STANDARD OF CARE (PVD OR DPD) IN LENALIDOMIDE-REFRACTORY MULTIPLE MYELOMA

Select TEAE ≥15%, n (%)	Safety population			
	Cilta-cel (n=208)		SOC (n=208)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Any AE	208 (100)	201 (96.6)	208 (100)	196 (94.2)
Serious AE	92 (44.2)	67 (32.2)	81 (38.9)	70 (33.7)
Hematologic	197 (94.7)	196 (94.2)	185 (88.9)	179 (86.1)
Neutropenia	187 (89.9)	187 (89.9)	177 (85.1)	171 (82.2)
Anemia	113 (54.3)	74 (35.6)	54 (26.0)	30 (14.4)
Thrombocytopenia	113 (54.3)	86 (41.3)	65 (31.3)	39 (18.8)
Lymphopenia	46 (22.1)	43 (20.7)	29 (13.9)	25 (12.0)
Infections	129 (62.0)	56 (26.9)	148 (71.2)	51 (24.5)
Upper respiratory tract[a]	39 (18.8)	4 (1.9)	54 (26.0)	4 (1.9)
Lower respiratory tract[b]	19 (9.1)	9 (4.3)	36 (17.3)	8 (3.8)
COVID-19[c]	29 (13.9)	6 (2.9)	55 (26.4)	12 (5.8)

- **Hematologic TEAEs most common**
  - 85–90% **neutropenia**, almost all grade 3/4
  - Most high-grade cytopenias **resolved to grade ≤2 by day 30**
  - Grade 3/4 infections similar between arms
- **Second primary malignancies:**
  - Cilta-cel, 4.3% (n=9); most commonly cutaneous/noninvasive and hematologic
  - SOC, 6.7% (n=14); most commonly cutaneous/noninvasive[d]
- **Deaths due to TEAEs**
  - Cilta-cel, n=10[e] (7 due to COVID-19[f])
  - SOC, n=5[g] (1 due to COVID-19)

Cilta-Cel im 1.-3. Rezidiv

S100: FIRST PHASE 3 RESULTS FROM CARTITUDE-4: CILTA-CEL VERSUS STANDARD OF CARE (PVD OR DPD) IN LENALIDOMIDE-REFRACTORY MULTIPLE MYELOMA

- **Cilta-cel significantly prolonged PFS vs SOC** (HR, 0.26; *P*<0.0001) in patients with lenalidomide-refractory MM and 1–3 prior LOT
  - **PFS benefit was seen across all subgroups**, including patients with high-risk cytogenetics (including in patients with 2 or more high-risk features), soft tissue plasmacytomas, ISS stage III disease, and prior exposure to anti-CD38 antibodies and PI
- Cilta-cel significantly increased ORR and depth of response vs SOC
  - ORR in the cilta-cel as-treated group was 99%, with 86% ≥CR and 72% MRD negative (10^{-5})
- **CAR-T–specific AEs were manageable** with appropriate supportive care
- Lower incidence and severity of CRS, ICANS, MNT, and some cytopenias were observed in CARTITUDE-4 vs CARTITUDE-1,[1,2] suggesting **improved tolerability of cilta-cel when used earlier in treatment**

Cilta-cel has the potential to be a new standard of care for patients with lenalidomide-refractory myeloma after first relapse

Kapitel 2

Ist negativ auch manchmal positiv? –

Belantamab mafodotin ab dem 2. Rezidiv

Belantamab mafodotin versus Pomalidomid/Dexamethason in RRMM

S199: A PHASE 3, OPEN-LABEL, RANDOMIZED STUDY EVALUATING THE EFFICACY AND SAFETY OF SINGLE AGENT BELANTAMAB MAFODOTIN VS POMALIDOMIDE PLUS DEXAMETHASONE IN RELAPSED/REFRACTORY MULTIPLE MYELOMA (DREAMM-3)

Meletios A. Dimopoulos, Vania Hungria, Atanas Radinoff, Sosana Delimpasi, Gabor Mikala, Tamas Masszi, Jian Li, Marcelo Eduardo Capra, Morio Matsumoto, Neal Sule, Mary Li, Astrid McKeown, Wei He, Shelley Bright, Brooke Currie, Julia Boyle, Joanna Opalinska, Katja Weisel

Belantamab mafodotin versus Pomalidomid/Dexamethason in RRMM

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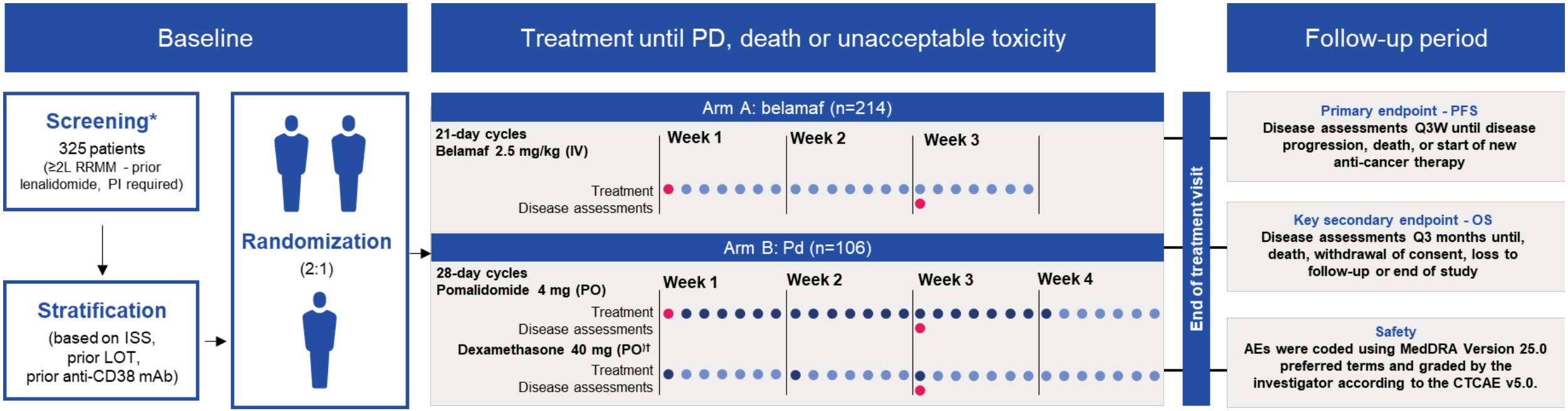

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Characteristic, n (%)	Belamaf N=218	Pd N=107
Age, median (range)	68 (43–86)	68 (38–90)
≥75 years	47 (22)	23 (21)
Male	118 (54)	66 (62)
High level Race		
White	162 (76)	84 (81)
Asian	47 (22)	19 (18)
Black or African American	3 (1)	1 (<1)
ISS stage at screening		
Stage I/II	165 (76)	78 (73)
Stage III	52 (24)	28 (26)
Extramedullary disease, yes	39 (18)	19 (18)
High Risk Cytogenetics^	57 (26)	34 (32)
Renal impairment per eGFR (mL/min/1·73m²)*		
Mild to moderate (≥30 to <90)	159 (73)	83 (78)
Prior lines of therapy, median (range)†	4 (2–12)	3 (2–13)
≤3 lines	108 (50)	54 (50)
>3 lines	110 (50)	53 (50)
≥6 lines	33 (15)	8 (7)
Prior daratumumab exposed, n (%)	88 (40)	41 (38)
Refractory to prior therapy		
Anti-CD38 mAb + PI + IMiD	46 (21)	22 (21)

Belantamab mafodotin versus Pomalidomid/Dexamethason in RRMM

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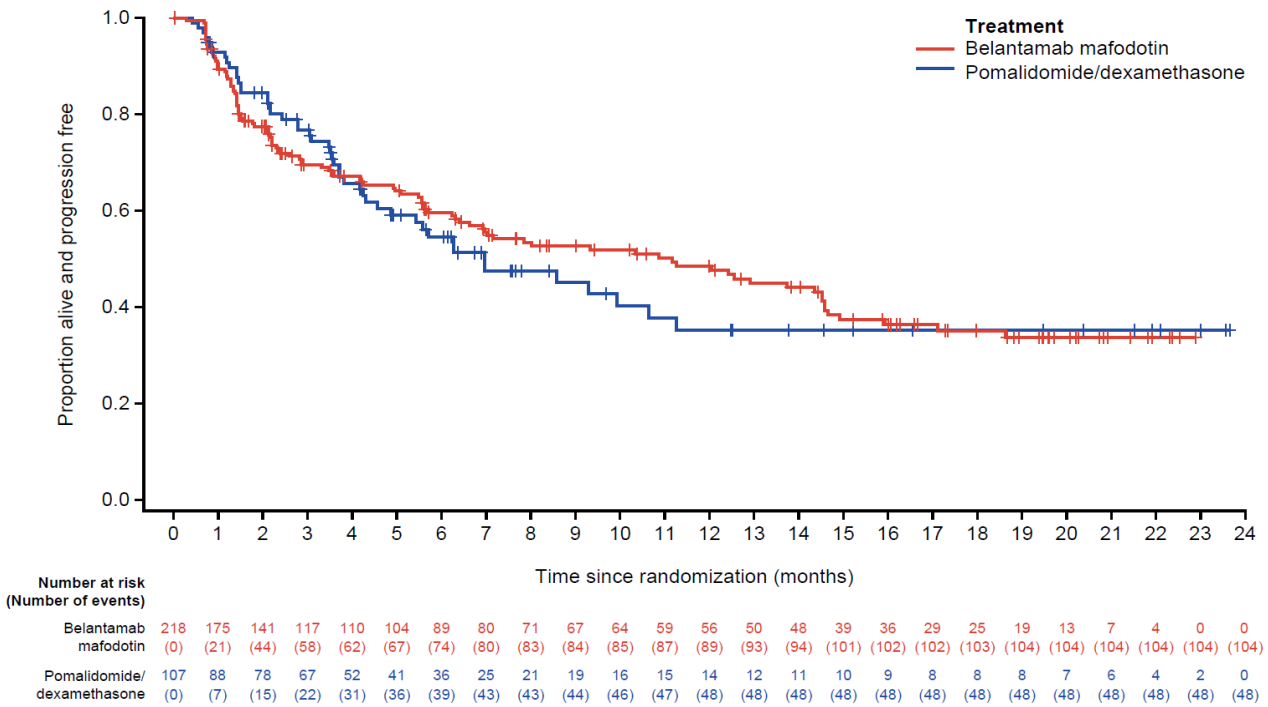
- Median follow-up was 11.5 months for belamaf and 10.8 months for Pd.
- Median PFS was longer for belamaf than for Pd, but PFS HR did not reach statistical significance.
  - Belamaf: **11.2** months (95% CI 6.4 – 14.5).
  - Pd: **7.0** months (95% CI 4.6 – 10.6).
  - HR of 1.03 (95% CI: 0.72, 1.47, p=0.558).
  - KM curves cross over at ~4 months.



Belantamab mafodotin versus Pomalidomid/Dexamethason in RRMM

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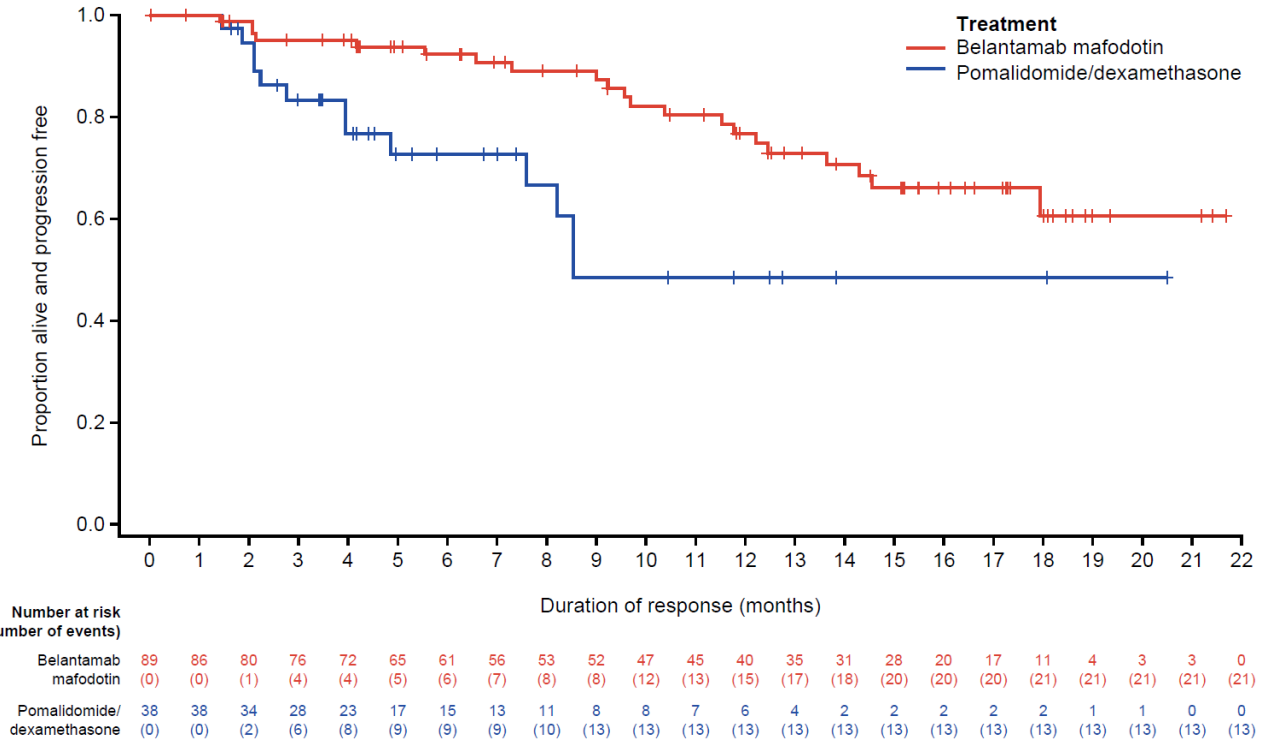
- Overall, median follow-up was 11.5 months for belamaf and 10.8 months for Pd.
- Median DoR* was longer for belamaf than for Pd:
  - Belamaf: **NR** (95% CI 17.9, NR).
  - Pd: **8.5** months (95% CI 7.6, NR).
  - Rates at
    - 6-month: 93% vs 75%.
    - 12-month: 77% vs 50%.
    - 18-month: 63% vs 50%.
- KM curves show clear and early separation.



Belantamab mafodotin versus Pomalidomid/Dexamethason in RRMM

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Treatment arm	Bilateral worsening of Snellen scores, n (%)	
	20/50 or worse	20/200 or worse*
Belamaf (n=217)	38 (18)	5 (2)
Pd (n=102)	1 (1)	0

Bilateral worsening of Snellen scores to 20/50 or worse	Belamaf N=38	Pd N=1
Time to first event onset, days, median (range)	62 (18–582)	84 (NA)
First event resolved†, n (% of patients)	36 (95)	1 (100)
Time to first event resolution, days, median (range)	40 (8–278)	85 (NA)

*At baseline, 1 patient had 20/20 in both eyes, 1 had 20/50 in both eyes, 1 had 20/100 in both eyes, and 2 patients had 20/100 in their worse eye. †Resolution was defined as returning to baseline level.
BCVA, best corrected visual acuity; Pd, pomalidomide plus dexamethasone

Belantamab mafodotin versus Pomalidomid/Dexamethason in RRMM

S199: A PHASE 3, OPEN-LABEL, RANDOMIZED STUDY EVALUATING THE EFFICACY AND SAFETY OF SINGLE AGENT BELANTAMAB MAFODOTIN VS POMALIDOMIDE PLUS DEXAMETHASONE IN RELAPSED/REFRACTORY MULTIPLE MYELOMA (DREAMM-3)

- Single-agent belamaf compared to Pd demonstrated:
  - Longer mPFS (11.2 vs 7.2 months), though PFS HR did not reach statistical significance.
  - Deeper (≥VGPR: 25% vs 8%) and more durable responses (mDoR NR vs 8.5 months at 11.5 months follow up).
- Survival data was only 37.5% mature and further follow-up is ongoing.
- No new safety signals were observed with single-agent belamaf; ocular toxicity was successfully managed with dose modifications.
- PRO data indicate that single-agent belamaf is a well-tolerated treatment option with a positive impact on important health outcomes for patients with third-line or greater RRMM.
- Further studies are currently investigating belamaf in combination regimens, and in earlier lines of therapy; results are eagerly awaited.

While the study did not meet its primary objective of demonstrating PFS superiority, single agent belamaf appears to show similar levels of clinical activity to a doublet regimen in RRMM

Kapitel 3

Bispezifische Antikörper – Sind wir bereit für Kombinationen?

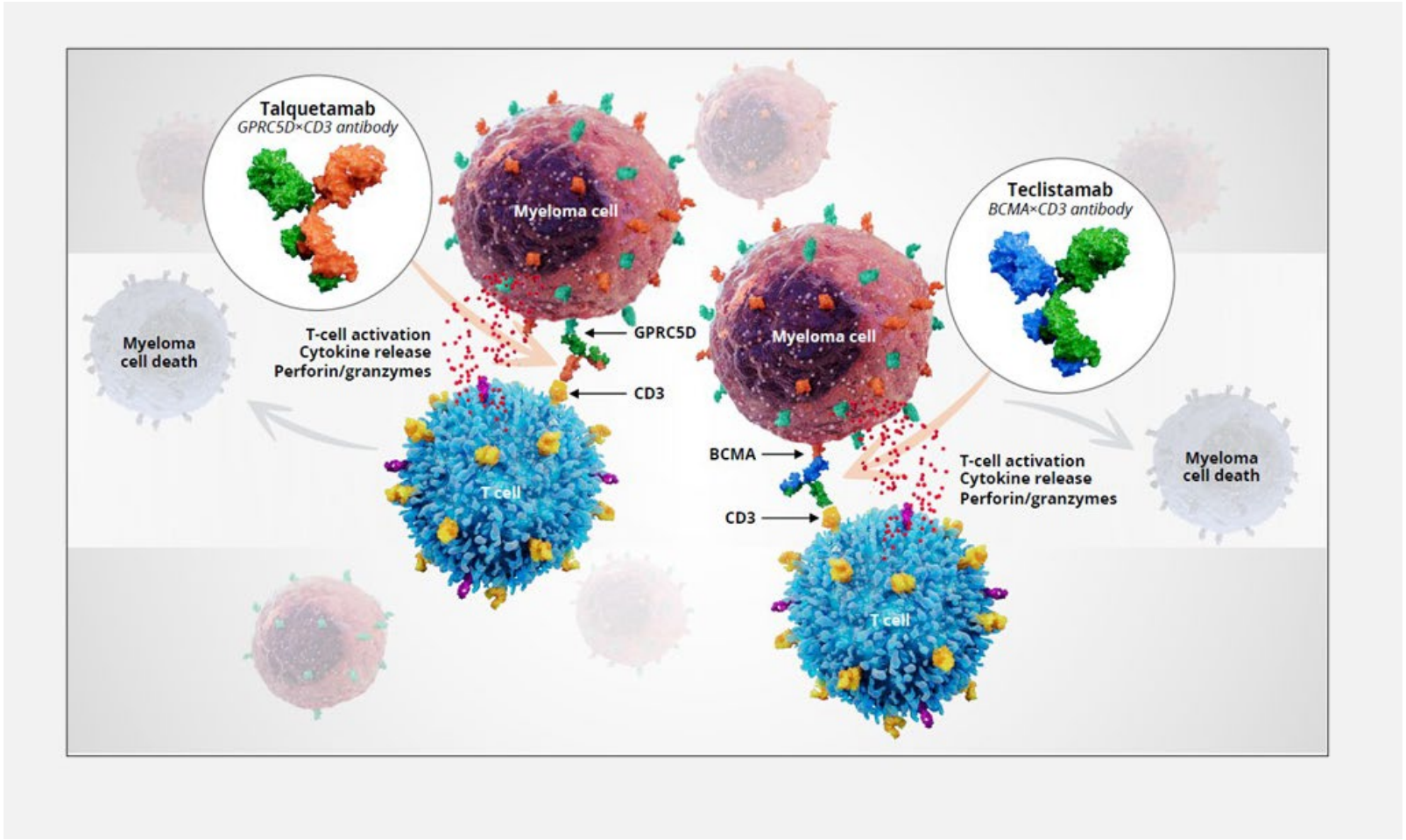
Teclistamab + Talquetamab Kombinations-Phase I Studie

S190: FIRST RESULTS FROM THE REDIRECTT-1 STUDY WITH TECLISTAMAB (TEC) + TALQUETAMAB (TAL) SIMULTANEOUSLY TARGETING BCMA AND GPRC5D IN PATIENTS (PTS) WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA (RRMM)

Maria-Victoria Mateos, Daniel Morillo, Moshe Gatt, Michael Sebag, Kihyun Kim, Chang-Ki Min, Albert Oriol, Enrique Ocio, Sung-Soo Yoon, Yael Cohen, Michael Chu, Paula Rodríguez-Otero, Irit Avivi, Yue Guo, Maria Krevvata, Michelle Peterson, Melissa Beelen, Jill Vanak, Arnob Banerjee, Hila Magen

Teclistamab + Talquetamab Kombinations-Phase I Studie

S190: FIRST RESULTS FROM THE REDIRECTT-1 STUDY WITH TECLISTAMAB (TEC) + TALQUETAMAB (TAL) SIMULTANEOUSLY TARGETING BCMA AND GPRC5D IN PATIENTS (PTS) WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA (RRMM)



Teclistamab + Talquetamab Kombinations-Phase I Studie

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Primary objectives

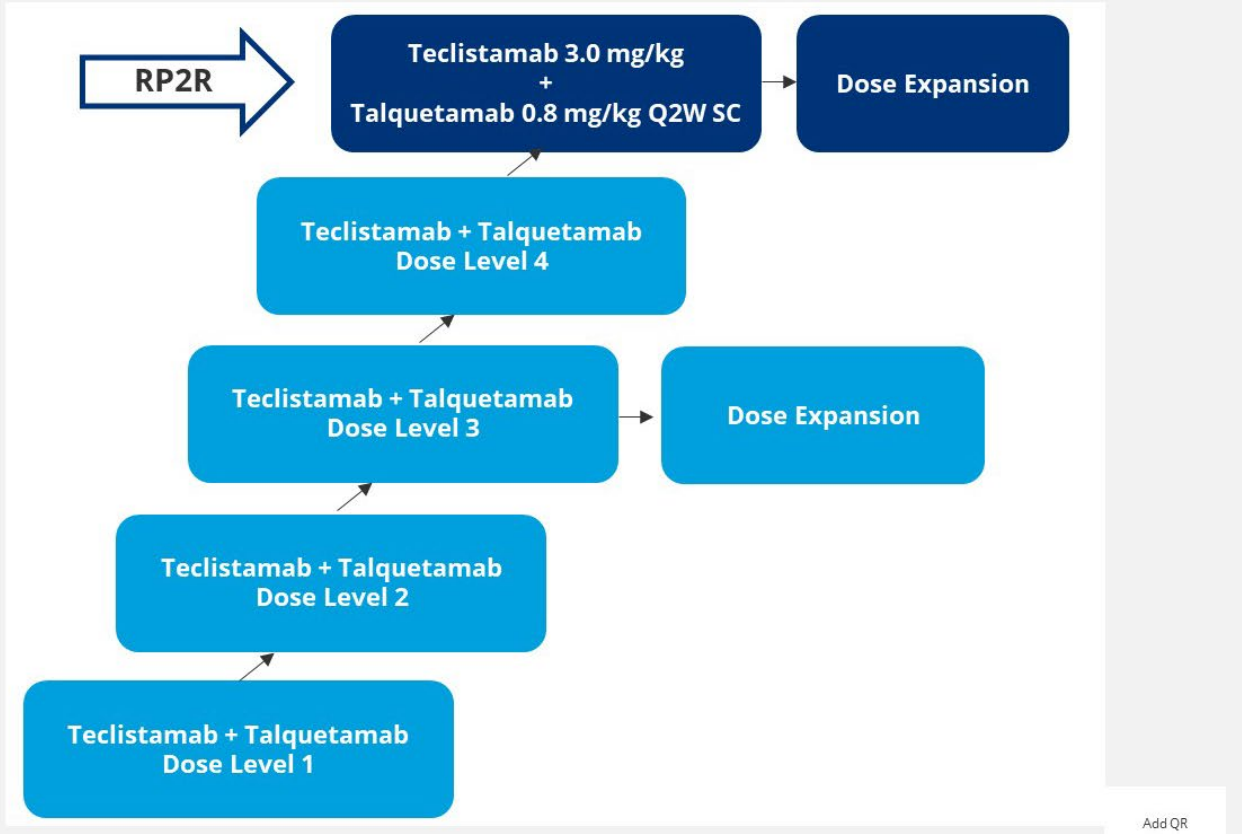
- Evaluate safety
- Identify RP2R(s) and schedule for the combination

Secondary objectives

- Preliminary anticancer activity of each study treatment at RP2R(s) in Part 2, PK, immunogenicity

Key eligibility criteria

- Measurable MM
- RR or intolerant to established therapies, including last LOT
- Exposed to a PI, IMiD, and anti-CD38 mAb



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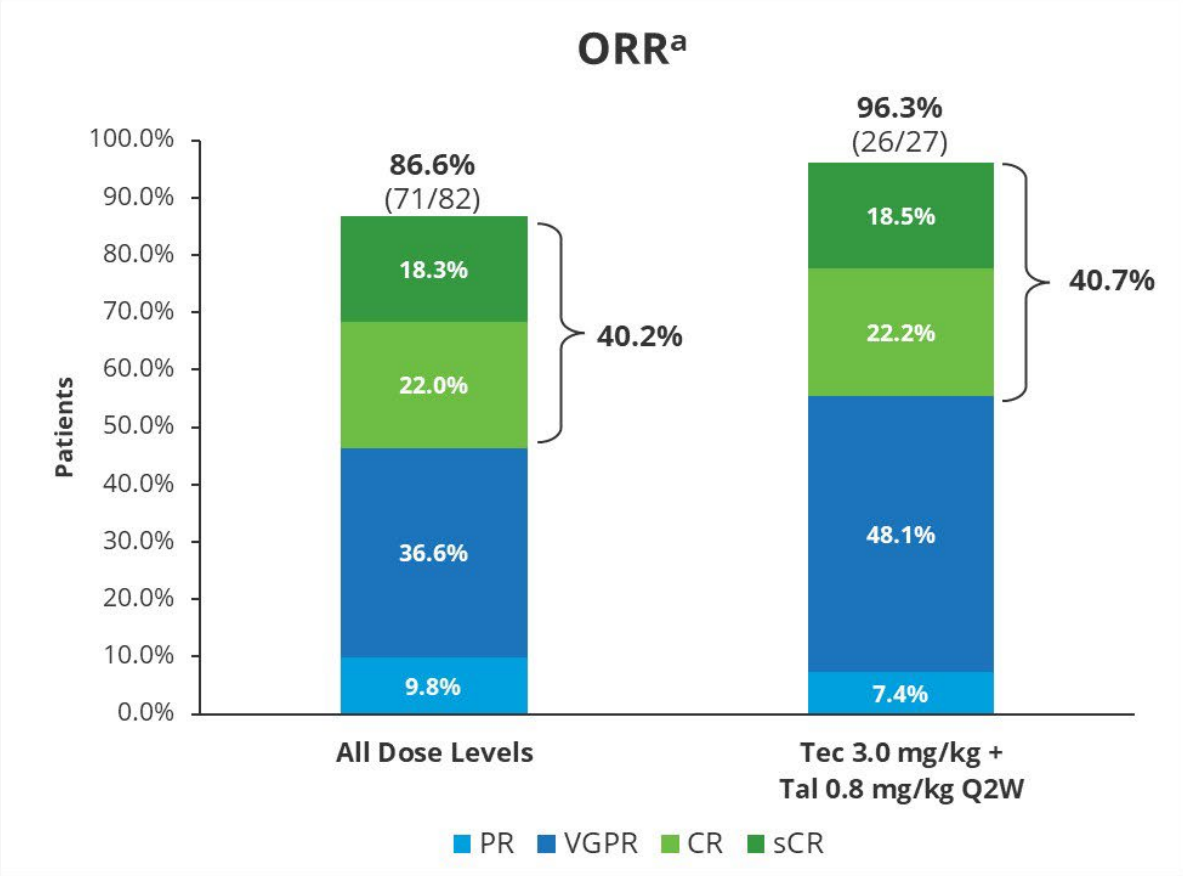

- ORR was high 86.6%) across dose levels studied and 96.3% at the RP2R
- At data cutoff, 61% (57/93) of patients remained on treatment

	All Dose Levels N=93	Tec 3.0 mg/kg + Tal 0.8 mg/kg Q2W n=34
Median follow-up, months (range)	13.4 (0.3–25.6)	8.1 (0.7–15.0)
Median DOR[b], months (95% CI)	NE (NE–NE)	NE (NE–NE)
Median time to first response[b], months (range)	1.97 (0–7.7)	1.48 (0–4.0)
Median time to best response[b], months (range)	3.98 (1.1–15.7)	3.22 (1.4–10.7)
Median PFS, months (95% CI)	20.9 (13.0–NE)	NE (9.9–NE)
9-month PFS rate (95% CI)	70.1 (58.0–79.4)	77.1 (50.8–90.5)

Teclistamab + Talquetamab Kombinations-Phase I Studie

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TEAE[a] (≥20% overall), n (%)	All Dose Levels N=93		Tec 3.0 mg/kg + Tal 0.8 mg/kg Q2W n=34	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Hematologic TEAEs				
Neutropenia	61 (65.6)	57 (61.3)	19 (55.9)	15 (44.1)
Anemia	47 (50.5)	32 (34.4)	11 (32.4)	8 (23.5)
Thrombocytopenia	40 (43.0)	27 (29.0)	11 (32.4)	8 (23.5)

TEAE[a] (≥25% overall), n (%)	All Dose Levels N=93		Tec 3.0 mg/kg + Tal 0.8 mg/kg Q2W n=34	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Nonhematologic TEAEs				
CRS	71 (76.3)	3 (3.2)	25 (73.5)	0
Dysgeusia[b,c]	57 (61.3)	--	16 (47.1)	--
Pyrexia	47 (50.5)	2 (2.2)	13 (38.2)	1 (2.9)
Skin toxicity[d]	50 (53.8)	0	18 (52.9)	0
Nail disorders[e]	43 (46.2)	0	14 (41.2)	0
Diarrhea	38 (40.9)	2 (2.2)	14 (41.2)	1 (2.9)
Cough	36 (38.7)	0	8 (23.5)	0
Dry mouth	35 (37.6)	0	11 (32.4)	0

- The majority of CRS events occurred during step-up dosing or cycle 1
- All CRS events resolved/were resolving at data cutoff

TEAE[a] (≥5% overall), n (%)	Total N=93		Tec 3.0 mg/kg + tal 0.8 mg/kg Q2W n=34	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Infections	**78 (83.9)**	**49 (52.7)**	**27 (79.4)**	**13 (38.2)**
COVID-19	31 (33.3)	9 (9.7)	14 (41.2)	1 (2.9)
Pneumonia	25 (26.9)	10 (10.8)	4 (11.8)	2 (5.9)
Upper respiratory tract infection	11 (11.8)	2 (2.2)	4 (11.8)	0
Nasopharyngitis	8 (8.6)	0	2 (5.9)	0
Rhinovirus infection	8 (8.6)	2 (2.2)	2 (5.9)	0
Oral candidiasis	7 (7.5)	1 (1.1)	2 (5.9)	0
Septic shock	7 (7.5)	6 (6.5)	1 (2.9)	1 (2.9)
Urinary tract infection	7 (7.5)	1 (1.1)	5 (14.7)	1 (2.9)
COVID-19 pneumonia	6 (6.5)	5 (5.4)	4 (11.8)	3 (8.8)
Bacteremia	5 (5.4)	2 (2.2)	1 (2.9)	0
Bronchitis	5 (5.4)	2 (2.2)	0	0
Sinusitis	5 (5.4)	0	1 (2.9)	0

Zusammenfassung | Take-Home-Messages

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- Cilta cel ist neuer Standard ab dem 1. Rezidiv für Lenalidomid-refraktäre Patient:innen
- Belantamab mafodotin ist als Monotherapie dem Pd Doublet nicht überlegen; Patient:innen, die auf Belamaf ansprechen zeigen lang-anhaltende Remissionen
- Bispezifische Antikörperkombinationen sind möglich und zeigen erste vielversprechende Effiktivitätsdaten

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- Auch bei rascher Zulassungserweiterung bleibt die Verfügbarkeit eine strukturelle Herausforderung
- Dexamethason-freie Monotherapien können gleiche Potenz wir Dubletten erreichen, Daten zu Kombinationstherapien werden bald erwartet
- Randomisierte Vergleiche zu bispezifischen Antikörpern fehlen, es gibt bislang nur wenige PFS Daten, Infektionsraten bleiben eine große Herausforderung

Die Kurzpräsentationen sind online unter

www.lymphome.de/eha2023

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