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# Neues vom amerikanischen Hämatologenkongress Multiples Myelom

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Medical Clinic V





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**Disclosures**

- Honoraria
  - Amgen, BMS, Celgene, Chugai, GSK, Janssen, Novartis, Sanofi
- Consulting or advisory role
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# PERSEUS

## Phase 3 Randomized Study of Daratumumab + Bortezomib, Lenalidomide, and Dexamethasone (VRd) Versus VRd Alone in Patients With Newly Diagnosed Multiple Myeloma Who Are Eligible for Autologous Stem Cell Transplantation: Primary Results of the PERSEUS Trial\*

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## PERSEUS: Baseline Demographic and Clinical Characteristics

	D-VRd (n = 355)	VRd (n = 354)
Age		
Median (range), years	61.0 (32-70)	59.0 (31-70)
Category, n (%)		
<50 years	54 (15.2)	54 (15.3)
≥50 and <65 years	207 (58.3)	213 (60.2)
≥65 years	94 (26.5)	87 (24.6)
Male, n (%)	211 (59.4)	205 (57.9)
ECOG PS, <sup>a</sup> n (%)		
0	221 (62.3)	230 (65.0)
1	114 (32.1)	108 (30.5)
2	19 (5.4)	16 (4.5)
3	1 (0.3)	0
MM diagnosis, n (%)		
N	354	352
CRAB criteria only <sup>b</sup>	125 (35.3)	113 (32.1)
Biomarkers of malignancy only	52 (14.7)	65 (18.5)
CRAB criteria and biomarkers of malignancy	177 (50.0)	174 (49.4)

	D-VRd (n = 355)	VRd (n = 354)
ISS stage, <sup>c</sup> n (%)		
N	355	353
I	186 (52.4)	178 (50.4)
II	114 (32.1)	125 (35.4)
III	55 (15.5)	50 (14.2)
Number of extramedullary plasmacytomas, n (%)		
0	340 (95.8)	338 (95.5)
≥1	15 (4.2)	16 (4.5)
Cytogenetic profile, <sup>d</sup> n (%)		
Standard risk	264 (74.4)	266 (75.1)
High risk	76 (21.4)	78 (22.0)
Indeterminate	15 (4.2)	10 (2.8)

### • D-VRd and VRd treatment arms were well balanced

MM, multiple myeloma; CRAB, calcium, renal, anemia, bone. <sup>a</sup>ECOG PS is scored on a scale from 0 to 5, with 0 indicating no symptoms and higher scores indicating increasing disability. One patient had an ECOG PS score of 0 at randomization that worsened to a score of 3 at baseline. <sup>b</sup>≥1 of the CRAB criteria. <sup>c</sup>Based on the combination of serum β2-microglobulin and albumin levels. Higher stages indicate more advanced disease. <sup>d</sup>Based on fluorescence in situ hybridization; high risk was defined as the presence of del(17p), t(4;14), and/or t(14;16).

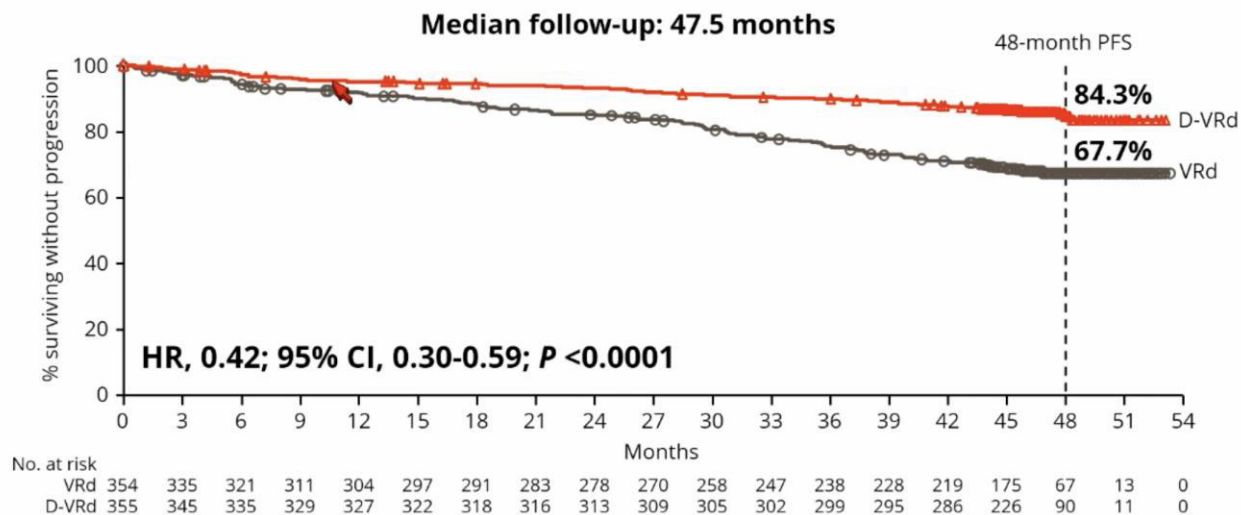
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# PERSEUS

## PERSEUS: Progression-free Survival



• 58% reduction in the risk of progression or death in patients receiving D-VRd



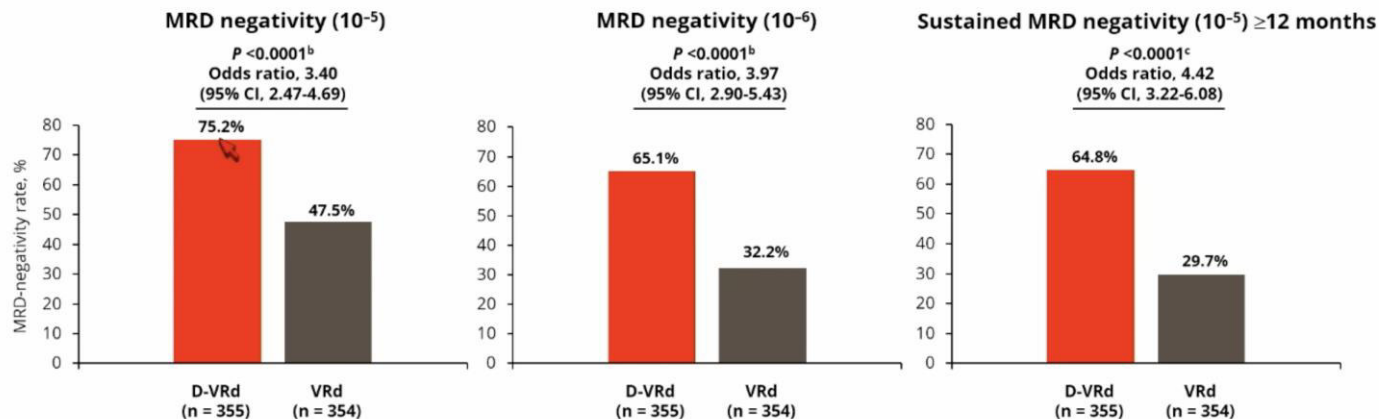
HR, hazard ratio; CI, confidence interval.

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# PERSEUS

## PERSEUS: Overall and Sustained MRD-negativity Rates<sup>a</sup>



- Deep and durable MRD negativity was achieved with D-VRd
- 64% (207/322) of patients receiving maintenance in the D-VRd group discontinued DARA after achieving sustained MRD negativity per protocol<sup>d</sup>

<sup>a</sup>MRD-negativity rate was defined as the proportion of patients who achieved both MRD negativity and  $\geq$ CR. MRD was assessed using bone marrow aspirates and evaluated via next-generation sequencing (clonoSEQ assay, version 2.0; Adaptive Biotechnologies, Seattle, WA). <sup>b</sup>P values were calculated with the use of the stratified Cochran-Mantel-Haenszel chi-squared test. <sup>c</sup>P value was calculated with the use of Fisher's exact test. <sup>d</sup>After  $\geq 24$  months of maintenance therapy, DARA was discontinued in patients who achieved  $\geq$ CR and sustained MRD negativity ( $10^{-5}$ ) for  $\geq 12$  months.

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## PERSEUS: Safety

Event, n (%) <sup>a</sup>	D-VRd (n = 351)		VRd (n = 347)	
	Any grade	Grade 3 or 4	Any grade	Grade 3 or 4
<b>HEMATOLOGIC</b>				
<b>Neutropenia</b>	<b>243 (69.2)</b>	<b>218 (62.1)</b>	<b>204 (58.8)</b>	<b>177 (51.0)</b>
<b>Thrombocytopenia</b>	<b>170 (48.4)</b>	<b>102 (29.1)</b>	<b>119 (34.3)</b>	<b>60 (17.3)</b>
Anemia	78 (22.2)	21 (6.0)	72 (20.7)	22 (6.3)
Febrile neutropenia	34 (9.7)	33 (9.4)	38 (11.0)	35 (10.1)
<b>NON-HEMATOLOGIC</b>				
Diarrhea	214 (61.0)	37 (10.5)	188 (54.2)	27 (7.8)
<b>Peripheral sensory neuropathy</b>	<b>188 (53.6)</b>	<b>15 (4.3)</b>	<b>179 (51.6)</b>	<b>14 (4.0)</b>
Constipation	119 (33.9)	8 (2.3)	118 (34.0)	6 (1.7)
Pyrexia	111 (31.6)	8 (2.3)	109 (31.4)	9 (2.6)
Insomnia	95 (27.1)	8 (2.3)	61 (17.6)	6 (1.7)
Asthenia	94 (26.8)	12 (3.4)	89 (25.6)	9 (2.6)
Cough	85 (24.2)	1 (0.3)	51 (14.7)	0
Fatigue	84 (23.9)	10 (2.8)	92 (26.5)	18 (5.2)
Rash	82 (23.4)	9 (2.6)	94 (27.1)	17 (4.9)
Back pain	80 (22.8)	2 (0.6)	66 (19.0)	1 (0.3)
Peripheral edema	72 (20.5)	4 (1.1)	74 (21.3)	1 (0.3)
Nausea	71 (20.2)	2 (0.6)	58 (16.7)	2 (0.6)
<b>Infections</b>	<b>305 (86.9)</b>	<b>124 (35.3)</b>	<b>266 (76.7)</b>	<b>95 (27.4)</b>
COVID-19	123 (35.0)	12 (3.4)	83 (23.9)	4 (1.2)
Upper respiratory tract infection	111 (31.6)	2 (0.6)	87 (25.1)	6 (1.7)
Pneumonia	64 (18.2)	37 (10.5)	38 (11.0)	21 (6.1)

TEAE, treatment-emergent adverse event. <sup>a</sup>TEAEs of any grade reported in ≥20% of patients in either treatment group and grade 3 or 4 TEAEs reported in ≥10% of patients in either treatment group.

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# PERSEUS

## PERSEUS Primary Analysis: Conclusions

- D-VRd (DARA SC) induction followed by ASCT, D-VRd consolidation, and D-R maintenance significantly improved PFS versus VRd induction followed by ASCT, VRd consolidation, and R maintenance in transplant-eligible patients with NDMM (HR, 0.42;  $P < 0.0001$ )
  - 48-month PFS rates: 84.3% versus 67.7%
- D-VRd regimen significantly improved depth of response versus VRd regimen
  - Overall  $\geq$ CR rates: 87.9% versus 70.1%
  - Overall MRD-negativity rates: 75.2% versus 47.5%
  - 64% of patients receiving D-R maintenance for at least 2 years were able to stop DARA after achieving sustained MRD negativity
- Observed safety profile was consistent with the known safety profiles for DARA SC and VRd

**• These randomized phase 3 results support D-VRd followed by D-R maintenance as a new standard of care for transplant-eligible patients with NDMM**



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# The Phase 2 CARTITUDE-2 Trial: Updated Efficacy and Safety of Ciltacabtagene Autoleucel in Patients With Multiple Myeloma and 1–3 Prior Lines of Therapy (Cohort A) and With Early Relapse After First Line Treatment (Cohort B)

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# CARTITUDE-2 Cohorts A & B: Introduction

- In CARTITUDE-1, a single cilta-cel infusion yielded deep and durable responses in heavily pretreated patients with RRMM<sup>1,2</sup>
  - Basis for approval in patients with RRMM with  $\geq 3$  and  $\geq 4$  prior LOT in Europe and the US, respectively<sup>3,4</sup>
- CARTITUDE-2 is a multicohort study of cilta-cel use in patients as early as after 1 prior LOT<sup>5-7</sup>
  - Cohorts A and B have the potential to yield insight into cilta-cel outcomes in patients in early LOT RRMM, a high unmet need

## Cohort A: Len-refractory MM after 1–3 prior LOT, including a PI and IMiD

ORR, 95% (90%  $\geq$ CR) as previously reported<sup>5</sup>

## Cohort B: 1 prior LOT, including a PI and IMiD, and PD $\leq 12$ months after ASCT or from the start of antimyeloma therapy

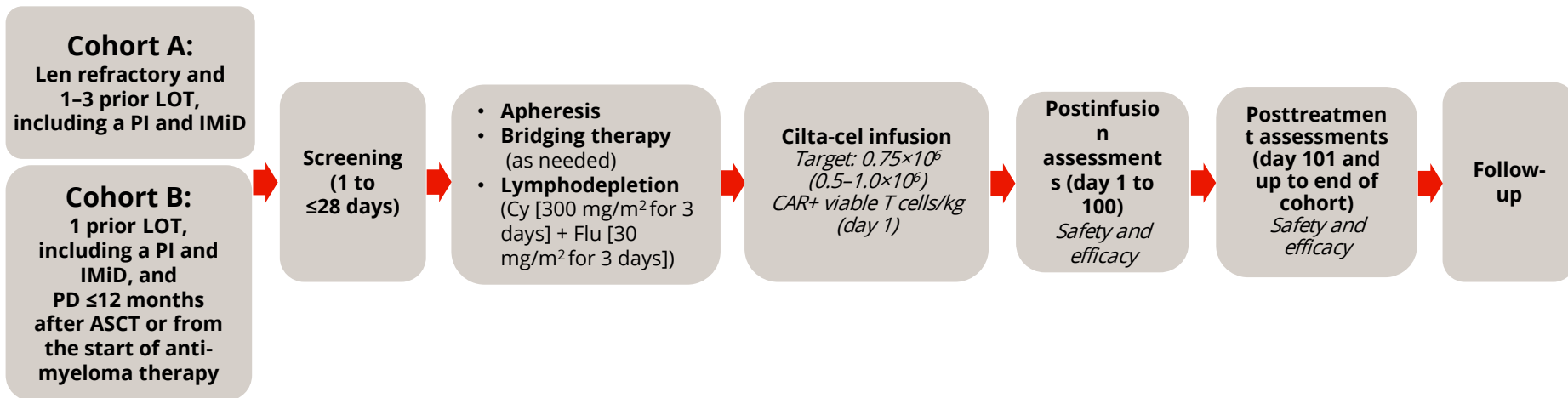
ORR, 100% (90%  $\geq$ CR) as previously reported<sup>6</sup>

**Objective: To report updated efficacy and safety data from CARTITUDE-2 cohorts A and B after a median follow-up of ~29 months**

ASCT, autologous stem cell transplant; cilta-cel, ciltacabtagene autoleucel; CR, complete response; IMiD, immunomodulatory drug; len, lenalidomide; LOT, line of therapy; MM, multiple myeloma; ORR, overall response rate; PD, progressive disease; PI, proteasome inhibitor; RRMM, relapsed/refractory MM. 1. Berdeja JG, et al. *Lancet* 2021;398:314-24. 2. Martin, T et al. *J Clin Oncol* 2023;41:1265-74. 3. CARVYKTI® (ciltacabtagene autoleucel). Prescribing information. Janssen Biotech, Inc.; 2023. 4. CARVYKTI® (ciltacabtagene autoleucel). European Medicines Agency. Orphan maintenance assessment report. June 7, 2022. Accessed November 27, 2023. 5. Einsele H, et al. *J Clin Oncol* 2022;40(suppl 16):8020. 6. van de Donk NWCJ, et al. *Blood* 2022;140(suppl 1):7536-7. 7. ClinicalTrials.gov, NCT04133636.



# CARTITUDE-2 Cohorts A & B: Study Design and Methods



- **Primary endpoint:** MRD negativity<sup>a</sup> ( $10^{-5}$  threshold) assessed by NGS or NGF
- **Secondary endpoints included:** ORR,<sup>a</sup> DOR, time to response, incidence and severity of AEs,<sup>b</sup> including CRS and ICANS<sup>1,c</sup>
- **Exploratory endpoints included:** PFS and OS

<sup>a</sup>Assessed per IMWG criteria. <sup>b</sup>Assessed per CTCAE version 5.0. <sup>c</sup>Graded per ASTCT criteria. AE, adverse event; ASCT, autologous stem cell transplant; ASTCT, American Society of Transplantation and Cellular Therapy; CAR, chimeric antigen receptor; cilta-cel, ciltacabtagene autoleucel; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; Cy, cyclophosphamide; DOR, duration of response; Flu, fludarabine; ICANS, immune effector cell-associated neurotoxicity syndrome; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; len, lenalidomide; LOT, line of therapy; MRD, minimal residual disease; NGS, next-generation sequencing; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PI, proteasome inhibitor.

1. Lee DW, et al. *Biol Blood Marrow Transplant* 2019;25:625-38.



# CARTITUDE-2 Cohorts A & B: Patient Demographic and Baseline Characteristics

Characteristic	Cohort A (N=20)	Cohort B (N=19)
Age, median (range), y	60 (38–75)	58 (44–67)
Male, n (%)	13 (65.0)	14 (73.7)
Race, n (%)		
White	18 (90.0)	14 (73.7)
Black/African American	2 (10.0)	2 (10.5)
Asian	0	1 (5.3)
Not reported	0	2 (10.5)
Bone marrow plasma cells <sup>a</sup> ≥60%, n (%)	3 (15.0)	4 (21.1)
Extramedullary plasmacytomas, n (%)	3 (15.0)	3 (15.8)
Cytogenetic high risk, <sup>b</sup> n (%)	7 (35.0) <sup>c</sup>	3 (15.8) <sup>d</sup>
del17p	3 (15.0)	3 (15.8)
t(14;16)	5 (25.0)	0
t(4;14)	0	0
1q	0	0

Characteristic	Cohort A (N=20)	Cohort B (N=19)
Years since initial diagnosis to enrollment, median (range)	3.5 (0.7–8.0)	1.15 (0.5–1.9)
Prior LOT, median (range)	2 (1–3)	1 (1–1)
Previous stem cell transplantation, <sup>e</sup> n (%)		
Autologous	17 (85.0)	15 (78.9)
Exposure status, n (%)		
Triple-class <sup>f</sup>	13 (65.0)	4 (21.1)
Penta-drug exposed <sup>g</sup>	4 (20.0)	0
Refractory status, n (%)		
Triple-class <sup>f</sup>	8 (40.0)	3 (15.8)
Penta-drug refractory <sup>g</sup>	1 (5.0)	0
To last line of prior therapy	19 (95.0)	15 (78.9)

- As of April 2023, median follow-up of patients who received cilta-cel infusion was 29.9 months (range, 3.3<sup>h</sup>–35.6) in cohort A and 27.9 months (range, 5.2<sup>h</sup>–32.1) in cohort B

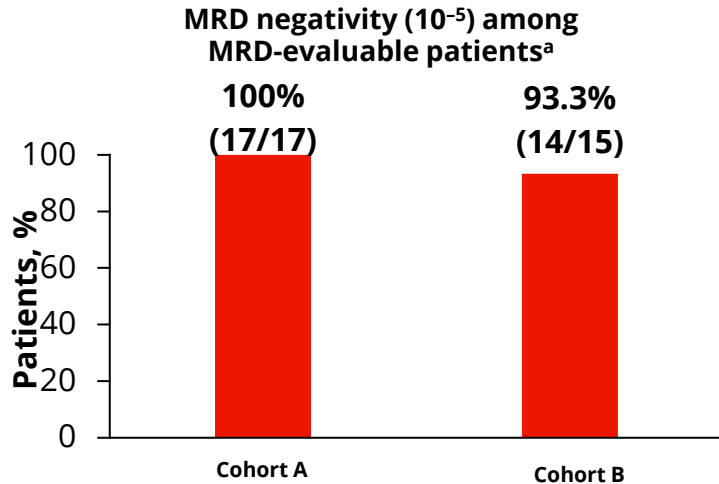
<sup>a</sup>Maximum value from bone marrow biopsy and bone marrow aspirate is selected if both results are available. <sup>b</sup>Any of the following 4 cytogenetic features abnormal: del17p, t(14;16), t(4;14), or 1q. <sup>c</sup>1 patient had both del17p and t(14;16); 6 (30.0%) patients had unknown cytogenetics. <sup>d</sup>3 (15.8%) patients had unknown cytogenetics. <sup>e</sup>17 patients in cohort A and 15 patients in cohort B received prior stem cell transplantation and all were autologous. <sup>f</sup>PI, IMiD, and anti-CD38 antibody. <sup>g</sup>≥2 PIs, ≥2 IMiDs, and 1 anti-CD38 antibody. <sup>h</sup>Includes patients who died. cilta-cel, ciltacabtagene autoleucel; IMiD, immunomodulatory drug; LOT, line of therapy; PI, proteasome inhibitor.



# CARTITUDE-2 Cohorts A & B: MRD Negativity (Primary Endpoint)

(~29-month median follow-up)

Most patients achieved MRD negativity at a threshold of  $10^{-5}$



Sustained MRD negativity <sup>b</sup>	Cohort A	Cohort B
<b>Patients evaluable for sustained MRD negativity <math>\geq 6</math> mo<sup>c</sup></b>	<b>n=11</b>	<b>n=13</b>
Sustained MRD negativity ( $10^{-5}$ ) $\geq 6$ mo, <sup>d</sup> n (%)	8 (72.7)	10 (76.9)
<b>Patients evaluable for sustained MRD negativity <math>\geq 12</math> mo<sup>e</sup></b>	<b>n=14</b>	<b>n=13</b>
Sustained MRD negativity ( $10^{-5}$ ) $\geq 12$ mo, <sup>f</sup> n (%)	7 (50.0)	8 (61.5)

Per protocol, bone marrow aspirate samples for MRD evaluation were collected at time of suspected CR/sCR; for all dosed patients at months 2, 6, 12, 18, and 24; and yearly thereafter for patients in CR/sCR.

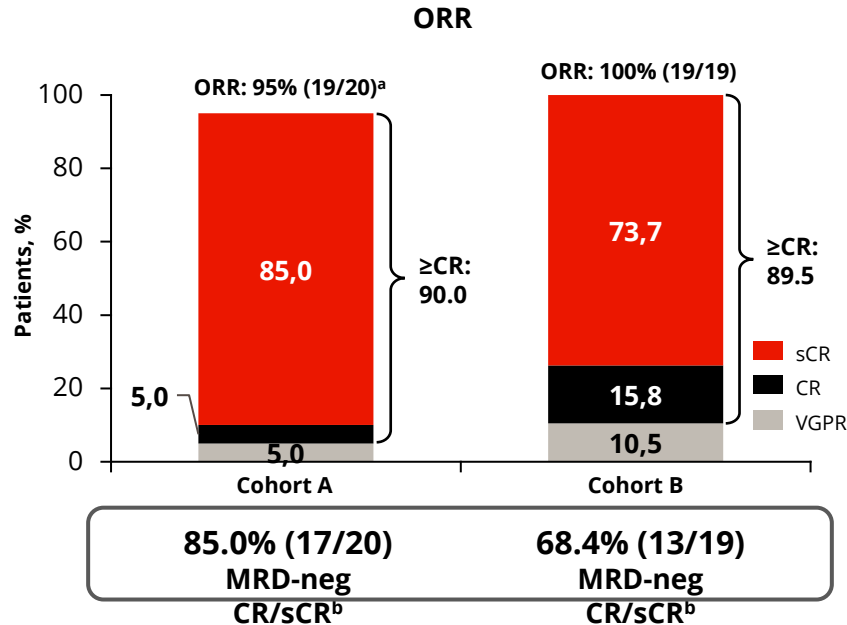
<sup>a</sup>Patients who were MRD evaluable had a clone identified and had at least 1 postbaseline MRD sample that included sufficient cells for evaluation at the  $10^{-5}$  testing threshold (for NGS) or patients who had at least 1 postbaseline sample with the result of either positive or negative (for NGF). <sup>b</sup>Post hoc analysis. <sup>c</sup>Patients who achieved overall MRD negativity and had at least an evaluable MRD sample at the  $10^{-5}$  testing threshold on or after 6 months after their first MRD negativity or progressed, started subsequent therapy, or died due to progressive disease within 6 months after their first MRD negativity. <sup>d</sup>MRD negative confirmed by at least 6 months apart without MRD positive in between. Percentage is calculated with number of patients evaluable for sustained MRD negativity  $\geq 6$  months as denominator. <sup>e</sup>Patients who achieved overall MRD negativity and had at least an evaluable MRD sample at the  $10^{-5}$  testing threshold on or after 12 months after their first MRD negativity or progressed, started subsequent therapy, or died due to progressive disease within 12 months after their first MRD negativity. <sup>f</sup>MRD negative confirmed by at least 12 months apart without MRD positive in between. Percentage is calculated with number of patients evaluable for sustained MRD negativity  $\geq 12$  months as denominator. CR, complete response; MRD, minimal residual disease; NGF, next-generation flow; NGS, next-generation sequencing; sCR, stringent CR.



# CARTITUDE-2 Cohorts A & B: Response (Secondary Endpoints)

(~29-month median follow-up)

## Cilta-cel led to deep and durable responses



Treatment response among responders	Cohort A (N=19)	Cohort B (N=19)
Time (mo) to first response, <sup>c</sup> median (range)	0.99 (0.7–3.3)	0.95 (0.9–9.7)
Time (mo) to best response, median (range)	3.25 (0.9–13.6)	5.1 (0.9–11.8)
<b>Duration of response</b>		
24-mo DOR rate, % (95% CI)	73.3 (47.2–87.9)	70.5 (42.5–86.7)

<sup>a</sup>1 patient had a minimal response. <sup>b</sup>Only MRD assessments (10<sup>-5</sup> testing threshold) within 3 months of achieving CR/sCR until death/progression/subsequent therapy (exclusive) are considered. <sup>c</sup>≥PR. cilta-cel, ciltacabtagene autoleucel; CR, complete response; DOR, duration of response; MRD, minimal residual disease; ORR, overall response rate; PR, partial response; sCR, stringent CR; VGPR, very good partial response.

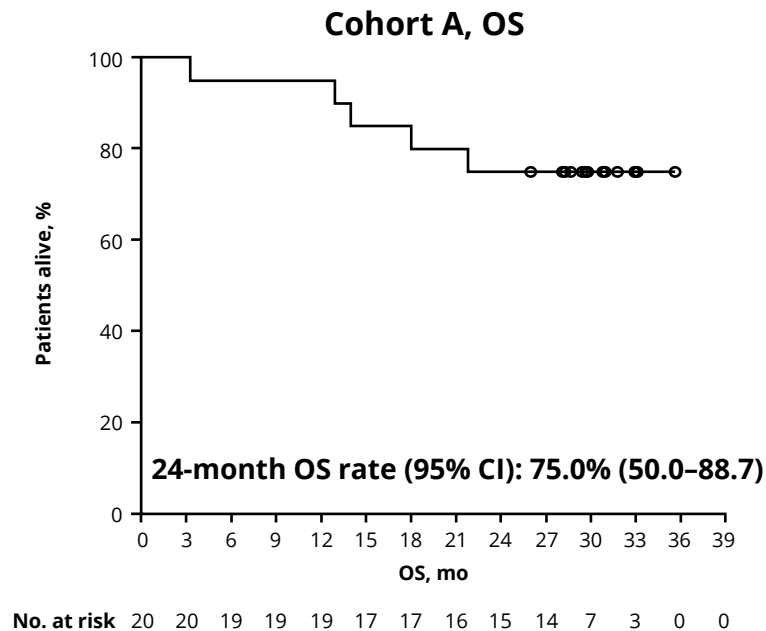
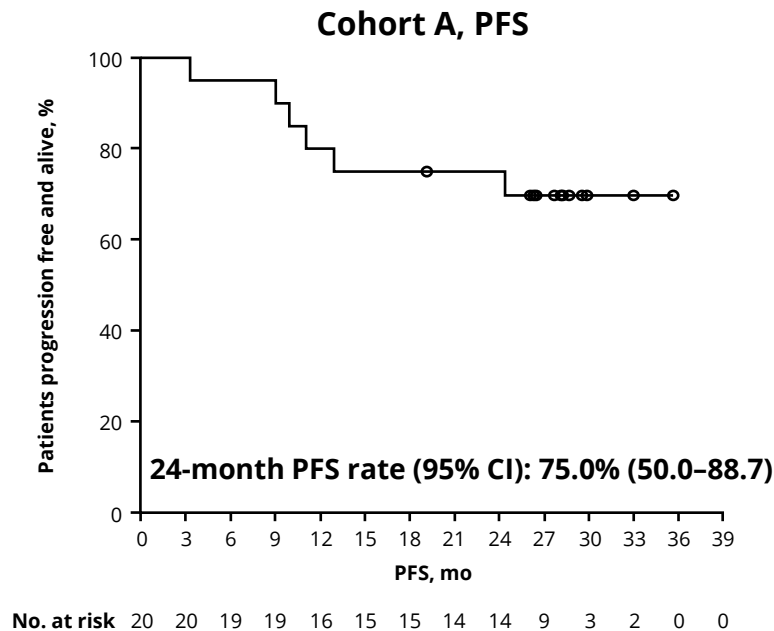




# CARTITUDE-2 Cohort A: PFS and OS (Exploratory Endpoints)

(~29-month median follow-up)

## PFS and OS maintained with additional follow-up



OS, overall survival; PFS, progression-free survival.

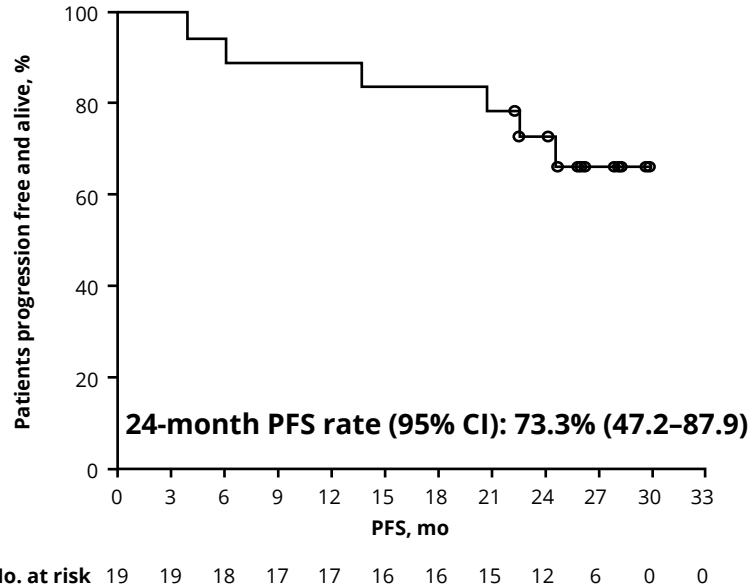


# CARTITUDE-2 Cohort B: PFS and OS (Exploratory Endpoints)

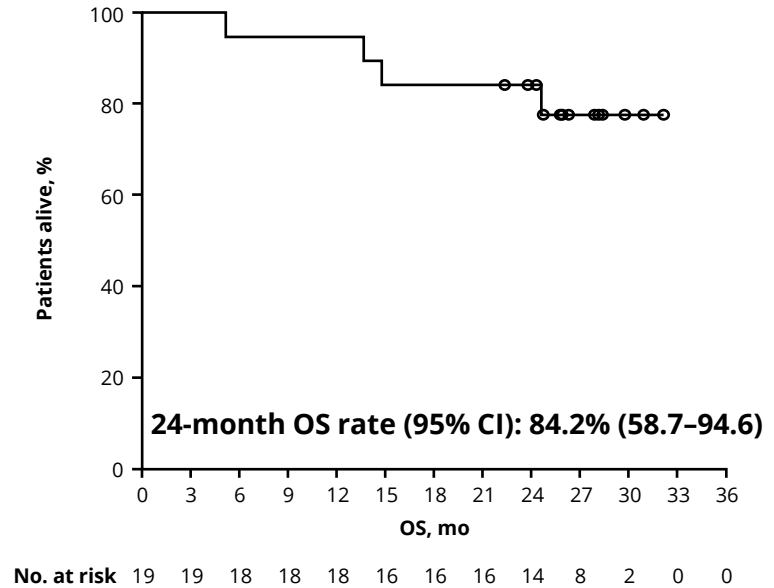
(~29-month median follow-up)

## PFS and OS maintained with additional follow-up

### Cohort B, PFS



### Cohort B, OS



OS, overall survival; PFS, progression-free survival.



# CARTITUDE-2 Cohorts A & B: AEs (Secondary Endpoint)

(~29-month median follow-up)

**AEs were predictable and consistent with the known safety profile of cilta-cel**

## Cohort A

- **Hematologic TEAEs<sup>a</sup> were most common**
  - 95.0% neutropenia, all grade 3/4
- **Second primary malignancies<sup>b</sup>:**
  - Grade 3 mucoepidermoid carcinoma, n=1
- **Deaths:** PD, n=3<sup>c</sup>; sepsis, n=1<sup>b</sup>; pneumonia, n=1<sup>d,e</sup>

## Cohort B

- **Hematologic TEAEs<sup>f</sup> were most common**
  - 94.7% neutropenia, almost all grade 3/4
- **Second primary malignancies<sup>b</sup>:**
  - Grade 2 prostate cancer, n=1
  - Grade 4 choroid melanoma, n=1<sup>g</sup>
- **Deaths:** PD, n=3; 1 cardiac arrest, n=1<sup>b,g</sup>

Select TEAEs, n (%)	Cohort A (N=20)		Cohort B (N=19)	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Any TEAE	20 (100.0)	19 (95.0)	19 (100.0)	18 (94.7)
Serious TEAE	10 (50.0)	–	7 (36.8)	–
<b>Hematologic</b>				
Neutropenia	19 (95.0)	19 (95.0)	18 (94.7)	17 (89.5)
Lymphopenia	16 (80.0)	16 (80.0)	9 (47.4)	9 (47.4)
Thrombocytopenia	16 (80.0)	8 (40.0)	11 (57.9)	5 (26.3)
Anemia	15 (75.0)	9 (45.0)	11 (57.9)	9 (47.4)
Leukopenia	12 (60.0)	12 (60.0)	6 (31.6)	6 (31.6)

<sup>a</sup>Between a median follow-up of 17.1–29.9 months, new grade 3/4 cases of leukopenia (n=1), lymphopenia (n=2), and thrombocytopenia (n=1). <sup>b</sup>Not treatment related. <sup>c</sup>1 new death on day 666 since last data cut-off. <sup>d</sup>Patient also had an AE of sepsis in addition to COVID-19 pneumonia. <sup>e</sup>Treatment related. <sup>f</sup>No change since previous data cut-off. <sup>g</sup>New event since last data cut-off. AE, adverse event; cilta-cel, ciltacabtagene autoleucel; PD, progressive disease; TEAE, treatment-emergent AE.



# CARTITUDE-2 Cohorts A & B: Conclusions

(~29-month median follow-up)

## Cohort A: Len-refractory 1–3 prior LOT RRMM

- 100% of evaluable patients were MRD negative at  $10^{-5}$
- 85% sCR rate with 73% of responders remaining in response for  $\geq 24$  months
- 24-month PFS and OS rates were both 75%
- No new CAR-T-related safety signals were observed

## Cohort B: Progressed $\leq 12$ months after 1L therapy

- 93% of evaluable patients were MRD negative at  $10^{-5}$
- 74% sCR rate with 71% of responders remaining in response for  $\geq 24$  months
- 24-month PFS and OS rates were 73% and 84%, respectively
- No new CAR-T-related safety signals were observed

- A similar patient population to CARTITUDE-2 Cohort A was evaluated in the phase 3 CARTITUDE-4 trial<sup>1</sup>

**Longer-term results from CARTITUDE-2 cohorts A and B showed deep and durable responses in patients with MM, including in a len-refractory population as early as after first relapse, and in a functionally high-risk population who progressed on frontline therapy within 12 months**

1L, first line; CAR, chimeric antigen receptor; len, lenalidomide; LOT, line of therapy; MM, multiple myeloma; MRD, minimal residual disease; OS, overall survival; PFS, progression-free survival; RRMM, relapsed/refractory multiple myeloma; sCR, stringent complete response.

1. San-Miguel J, et al. *New Engl J Med* 2023;389:335-47.



# IFM2018-04



American Society of Hematology  
Helping hematologists conquer blood diseases worldwide

## Daratumumab Carfilzomib Lenalidomide and Dexamethasone induction and consolidation with tandem transplant in high-risk newly diagnosed myeloma patients: results of the phase 2 study IFM 2018-04

Cyrille Touzeau<sup>1</sup>, Aurore Perrot<sup>2</sup>, Cyrille Hulin<sup>3</sup>, Salomon Manier<sup>4</sup>, Margaret Macro<sup>5</sup>, Marie-Lorraine Chretien<sup>6</sup>, Lionel Karlin<sup>7</sup>, Martine Escoffre<sup>8</sup>, Caroline Jacquet<sup>9</sup>, Mourad Tiab<sup>10</sup>, Xavier Leleu<sup>11</sup>, Hervé Avet-Loiseau<sup>2</sup>, Alexandra Jobert<sup>12</sup>, Lucie Planche<sup>12</sup>, Jill Corre<sup>2</sup>, Philippe Moreau<sup>1</sup>

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# IFM2018-04

## 2018-04 Study design

### Key inclusion criteria:

- Age < 66
- Newly diagnosed multiple myeloma
- Transplant-eligible
- High-risk FISH : t(4;14), 17p Del, t(14;16)
- ECOG 0-2

### Objectives:

- **Primary Objective:** Feasibility  
primary endpoint : >70% patients receiving 2nd transplant
- **Secondary Objectives:** Safety, ORR, PFS, OS, stem-cell collection



<p><b>Dara : 16 mg/kg IV</b> D1,8,15,22 (cycle 1 and 2) D1 D15 (Cycle 3 to 6)</p> <p><b>K : (20)36 mg/m2 IV</b> D1-2, 8-9, 15-16</p> <p><b>Len : 25 mg D1-21</b></p> <p><b>Dex : 20 mg D1-2, 8-9, 15-16, 22-23</b></p> <p>28-day cycle</p>	<p>Cyclo GCSF +/- Plerix</p>	<p>Mel 200</p>	<p><b>Dara : 16 mg/kg IV D1 D15</b></p> <p><b>K : 56 mg/m2 IV D1, 8, 15</b></p> <p><b>Len : 15 mg D1-21</b></p> <p><b>Dex : 40 mg D1, 8, 15, 22</b></p> <p>28-day cycle</p>	<p>Mel 200</p>	<p><b>Dara : 16 mg/kg IV every 8 weeks</b></p> <p><b>Len : 10 mg 21/28</b></p>
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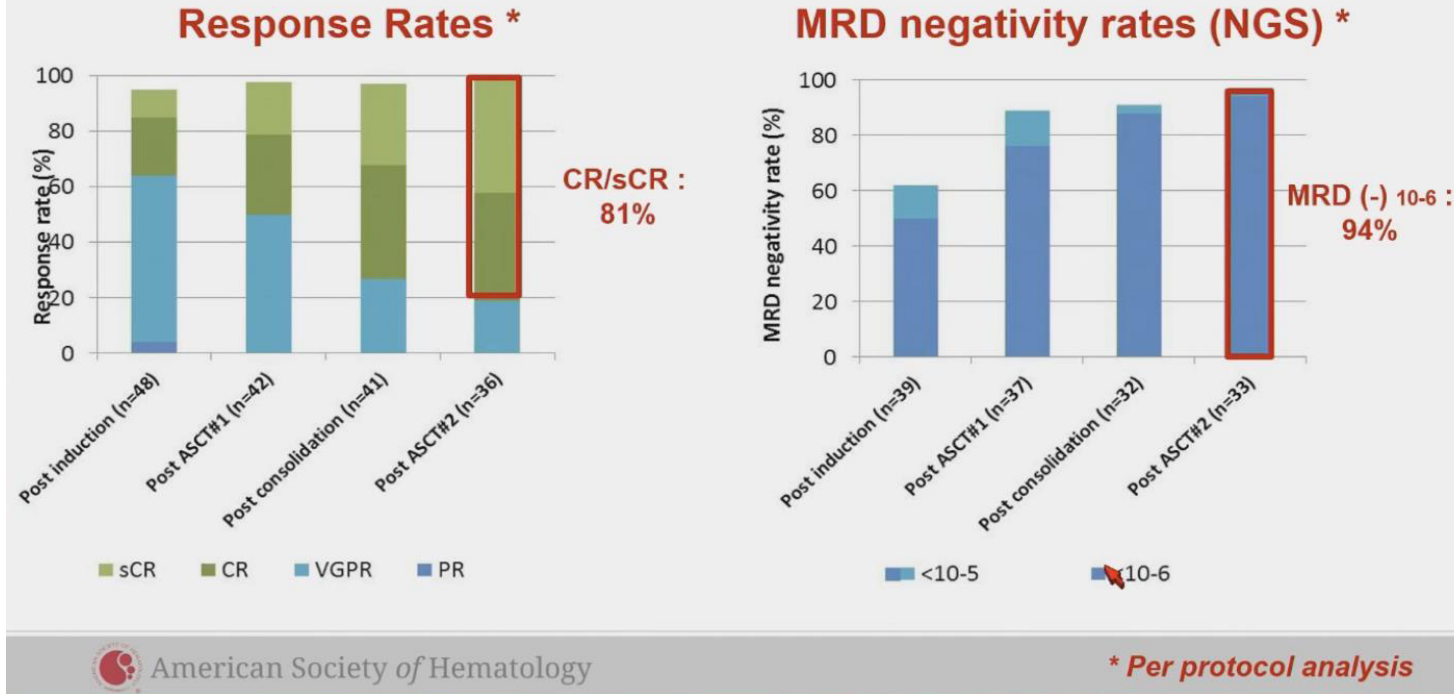
## Baseline characteristics

	N=50
<b>Median age (range), years</b>	57 (38-65)
<b>ECOG PS</b>	
0-1	47 (94%)
2	3 (6%)
<b>ISS score</b>	
stage 1	21 (42%)
stage 2	17 (34%)
stage 3	12 (24%)
<b>R-ISS score</b>	
stage 2	38 (76%)
stage 3	12 (24%)

	N=50
<b>Extramedullary disease</b>	4 (8%)
primary PCL	3 (6%)
<b>High-risk (HR) cytogenetics</b>	50 (100%)
del(17p)	20 (40%)
t(4;14)	26 (52%)
t(14;16)	10 (20%)
gain(1q)	25 (50%)
del(1p)	6 (12%)
<b>≥2 HR cytogenetic abnormalities *</b>	30 (60%)

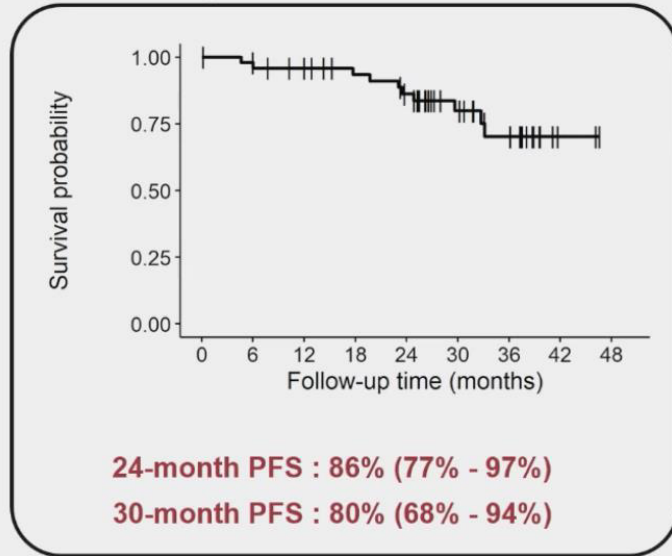
\* defined by the presence of 2 HR abnormalities among del(17p), t(4;14), t(14;16), gain(1q), del(1p)

## Response rates and MRD



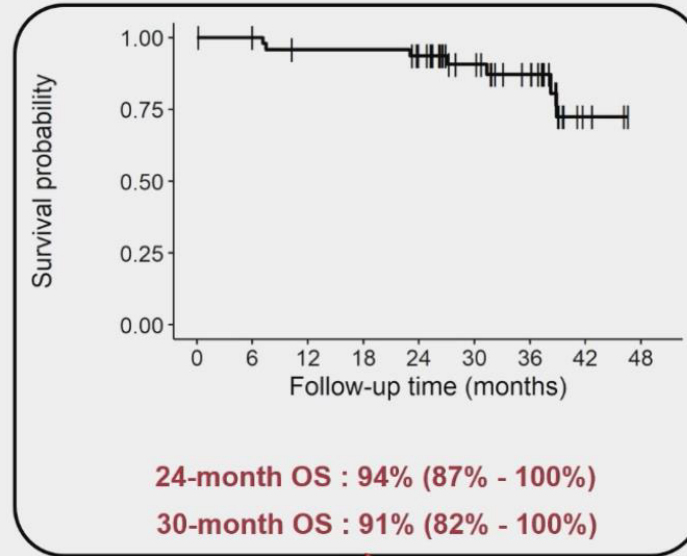
## Progression-free and Overall Survival

### Progression-free survival



8 patients had disease progression

### Overall Survival



7 patients died : disease prog (n=5) ; SAE (n=2)



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Median follow-up : 32 months

Data cut-off: may 2023



# EMN26

## Iberdomide Maintenance after Autologous Stem Cell Transplantation in Newly Diagnosed MM: First Results of the Phase 2 EMN26 Study

Niels W.C.J. Van De Donk<sup>1</sup>, Cyrille Touzeau<sup>2</sup>, Evangelos Terpos<sup>3</sup>, Aurore Perrot<sup>4</sup>, Roberto Mina<sup>5,6</sup>, Maaïke de Ruijter<sup>1</sup>, Elisabetta Antonioli<sup>7</sup>, Eirini Katodritou<sup>8</sup>, Norbert Pescosta<sup>9</sup>, Paulus A.F. Geerts<sup>10</sup>, Cécile Sonntag<sup>11</sup>, Ruth Wester<sup>12</sup>, Angelo Belotti<sup>13</sup>, Silvia Mangiacavalli<sup>14</sup>, Massimo Offidani<sup>15</sup>, Mattia D'Agostino<sup>5,6</sup>, Mark van Duin<sup>12</sup>, Michele Cavo<sup>16</sup>, Sara Aquino<sup>17</sup>, Alessandra Lombardo<sup>18</sup>, Mark-David Levin<sup>19</sup>, Cyrille Hulin<sup>20</sup>, Mario Boccadoro<sup>21</sup>, Pieter Sonneveld<sup>12</sup> and Francesca Gay<sup>5</sup>

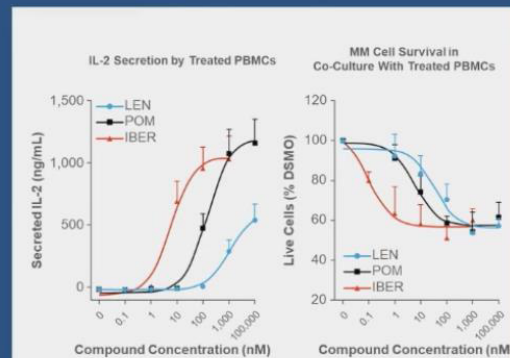
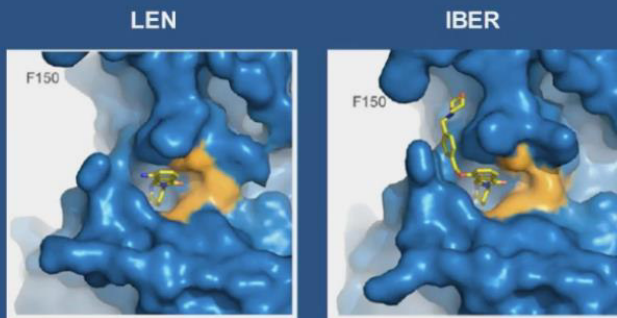
<sup>1</sup>Amsterdam UMC, Vrije Universiteit Amsterdam, Department of Hematology, Cancer Center Amsterdam, Amsterdam, Netherlands; <sup>2</sup>Department of Hematology, University Hospital Hôtel-Dieu, Nantes, France; <sup>3</sup>Department of Clinical Therapeutics, National and Kapodistrian University of Athens, School of Medicine, Athens, Greece; <sup>4</sup>Service d'Hématologie, CHU de Toulouse, Institut Universitaire du Cancer de Toulouse Oncopole, Université de Toulouse, Toulouse, France; <sup>5</sup>Division of Hematology, Department of Molecular Biotechnology and Health Sciences, University of Torino, Torino, Italy; <sup>6</sup>Division of Hematology, Azienda Ospedaliero-Universitaria Città della Salute e della Scienza di Torino, University of Torino, Torino, Italy; <sup>7</sup>Hematology Unit, ADU Careggi, Florence, Italy; <sup>8</sup>Department of Hematology, Theagenion Cancer Hospital, Thessaloniki, Greece; <sup>9</sup>Reparto Ematologia e TMND, Ospedale Provinciale Bolzano, Bolzano, Italy; <sup>10</sup>Isala Klinieken, Zwolle, Netherlands; <sup>11</sup>University Hospital, Hôpital Hautepierre, Strasbourg, France; <sup>12</sup>Department of Hematology, Erasmus MC Cancer Institute, Rotterdam, Netherlands; <sup>13</sup>Department of Hematology, ASST Spedali Civili di Brescia, Brescia, Italy; <sup>14</sup>Division of Hematology, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy; <sup>15</sup>ADU delle Marche, Ancona, Italy; <sup>16</sup>IRCCS Azienda Ospedaliero-Universitaria di Bologna, Seragnoli Institute of Hematology, and the Department of Medical and Surgical Sciences, Bologna University School of Medicine, Bologna, Italy; <sup>17</sup>Ematologia e Terapie cellulari, IRCCS Ospedale Policlinico San Martino, Genova, Italy; <sup>18</sup>A.O. Santa Maria di Terni - Università degli Studi di Perugia, Terni-Perugia, Italy; <sup>19</sup>Albert Schweitzer hospital, Dordrecht, Netherlands; <sup>20</sup>Centre Hospitalier Universitaire Bordeaux, Bordeaux, France; <sup>21</sup>European Myeloma Network, EMN, Italy



# EMN26

## EMN26: Introduction (2)

- Iberdomide (IBER) is a novel, potent, oral cereblon (CRBN) E3 ligase modulator (CELMoD™) with greater tumoricidal and immune-modulatory effects compared with IMiDs<sup>1-3</sup>
- Unlike lenalidomide, Iberdomide is administered as a single enantiomer (S isomer), maintained in vivo. This can help to avoid side effects such as sedation and fatigue attributed to the R isomer.
- IBER safety, efficacy, and pharmacodynamic data from the ongoing CC-220-MM-001 trial justify further investigation of this agent in the maintenance setting<sup>4</sup>
- **We present the initial results from the ongoing EMN26 phase 2 study with IBER maintenance after ASCT in patients with NDMM (NCT04564703)**



<sup>1</sup>Matyskiela ME, et al. *J Med Chem* 2018;61:535–542; <sup>2</sup>Amatangelo M, et al. *Blood* 2019;134(suppl 1). Abstract 1775; <sup>3</sup>Bjorklund CC, et al. *Leukemia* 2020;34:1197–1201; <sup>4</sup>Lonial S, et al. *Lancet Haematol* 2022;9:e822–e832.



# EMN26

## EMN26 is an ongoing, phase 2, multicohort study

### Key eligibility criteria

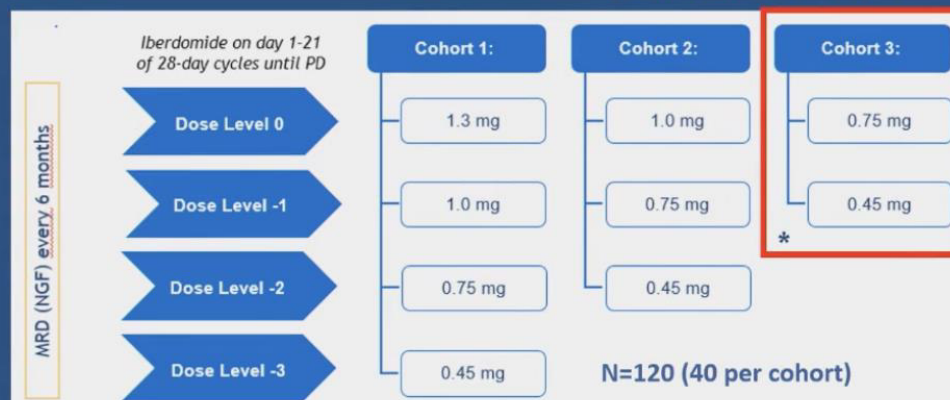
- NDMM patients,  $\geq$ PR after ASCT
- Subjects treated with proteasome inhibitor plus immunomodulatory drug-based induction (3-6 cycles), followed by single or double autologous stem cell transplant (ASCT) with melphalan as conditioning regimen +/- consolidation
- Subjects within 15 months from diagnosis and 120 days after last ASCT or consolidation treatment, if performed

### Primary endpoint

- Efficacy (response improvement within 6 months: PR to  $\geq$ VGPR; VGPR to  $\geq$ CR; CR to sCR) of the 3 different dose levels of iberdomide maintenance post-ASCT<sup>#</sup>

### Key secondary endpoints

- Rate of next-generation flow (NGF) minimal residual disease (MRD;  $10^{-5}$ ) conversion from positive to negative
- Rate of adverse events
- PFS, PFS2, OS, TTP, TTNT



NDMM, newly diagnosed multiple myeloma; PR, partial response; ASCT, autologous stem cell transplantation; PR, partial response; VGPR, very good partial response; CR, complete response; sCR, stringent complete response; PD, progressive disease; MRD, minimal residual disease; \*, cohort 3 was added at a later stage; #null hypothesis: response improvement rate within 6 month is  $\leq$  20%



# EMN26

## EMN26: Baseline demographics and Disease Characteristics (1)

Characteristic	IBER 1.3 mg PO (n=40)	IBER 1.0 mg PO (n=40)	IBER 0.75 mg PO (n=40)
Median (IQR) age, years	59 (51-66)	59 (55-64)	60 (52-65)
Male sex, n (%)	26 (65)	17 (42)	22 (55)
Type of myeloma at initial diagnosis, n (%)			
IgG	20 (50)	20 (50)	20 (50)
IgA	12 (30)	9 (22)	7 (17)
Light chain	7 (17)	10 (25)	13 (33)
Other	1 (3)	1 (3)	0
≥1 extramedullary plasmacytomas, n (%)	0	1 (3)	1 (3)
High-risk cytogenetics, <sup>a</sup> n (%)	7 (17)	8 (20)	10 (25)
ISS stage at diagnosis, n (%)			
I	14/40 (35)	16/39 (41)	21/38 (55)
II	14/40 (35)	13/39 (33)	11/38 (29)
III	12/40 (30)	10/39 (26)	6/38 (16)

Characteristic	IBER 1.3 mg PO (n=40)	IBER 1.0 mg PO (n=40)	IBER 0.75 mg PO (n=40)
R-ISS stage at diagnosis, n (%)			
I	9/40 (22)	12/39 (31)	15/37 (41)
II	25/40 (62)	22/39 (56)	19/37 (51)
III	6/40 (15)	5/39 (13)	3/37 (8)
ECOG performance status at study entry, n (%)			
0	28 (70)	23 (58)	27 (68)
1	12 (30)	17 (42)	13 (32)
Median (IQR) creatinine, mg/dL	0.81 (0.71/0.91)	0.79 (0.65/0.91)	0.78 (0.72/1.01)

Data cut-off November 8, 2023. <sup>a</sup>Cytogenetic risk is based on FISH and is defined as ≥1 of the following: del(17p), t(4;14), or t(14;16). FISH, fluorescence in situ hybridization; ISS, International Staging System; PO, oral.

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# EMN26

## EMN26: Baseline demographics and Disease Characteristics (2)

Characteristic	IBER 1.3 mg PO (n=40)	IBER 1.0 mg PO (n=40)	IBER 0.75 mg PO (n=40)
Induction type*			
VTD	12 (30)	19 (48)	2 (5)
VRD	13 (33)	7 (18)	3 (8)
D-VTD	12 (30)	13 (33)	33 (83)
D-VRD	3 (8)	1 (3)	2 (5)
Auto-SCT			
Single	34 (85)	30 (75)	36 (90)
Double	6 (15)	10 (25)	4 (10)
Consolidation			
No	35 (88)	36 (90)	22 (55)
Yes	5 (13)	4 (10)	18 (45)
Response at study entry			
sCR	7 (17)	6 (15)	8 (20)
CR	4 (10)	4 (10)	5 (12)
VGPR	26 (65)	25 (62)	22 (55)
PR	3 (7)	5 (12)	5 (12)

Characteristic	IBER 1.3 mg PO (n=40)	IBER 1.0 mg PO (n=40)	IBER 0.75 mg PO (n=40)
MRD status at study entry			
Negative	20 (50)	19 (48)	26 (65)
Positive	15 (38)	19 (48)	10 (25)
Not evaluable	5 (13)	2 (5)	4 (10)
Time from diagnosis to first maintenance dose (months)	10 (9-11)	10 (9-12)	12 (11-14)
Time from last ASCT to first maintenance dose (months)	4 (3-4)	3 (3-4)	4 (3-6)

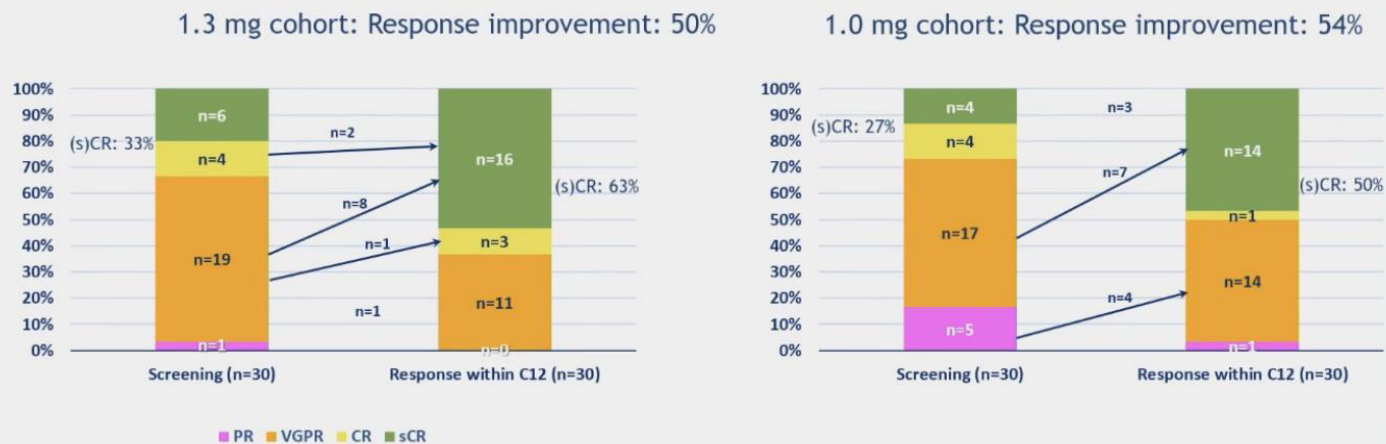
Data cut-off November 8, 2023. \*Cytogenetic risk is based on FISH and is defined as  $\geq 1$  of the following: del(17p), t(4;14), or t(14;16). \*Some patients exchanged one drug for another drug after initiation of induction treatment (most frequently exchange of thalidomide for cyclophosphamide in case of neuropathy)  
FISH, fluorescence in situ hybridization; ISS, International Staging System; PO, oral.

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# EMN26

## EMN26: Response improvement during first 12 cycles

→ responses improve over time



MRD conversion\*: 7/12 patients (58%) in 1.3 mg cohort and 5/17 patients (29%) in 1.0 mg cohort

\* MRD evaluated with next-generation flow cytometry with a sensitivity of 10<sup>-5</sup>; Conversion of MRD-positive to MRD-negative; calculated in patients who were MRD-positive at the time of screening and for whom a repeat bone marrow was done as scheduled at 12 months; patients who experienced earlier study discontinuation in the absence of MRD evaluation at 12 months were included in denominator

# EMN26

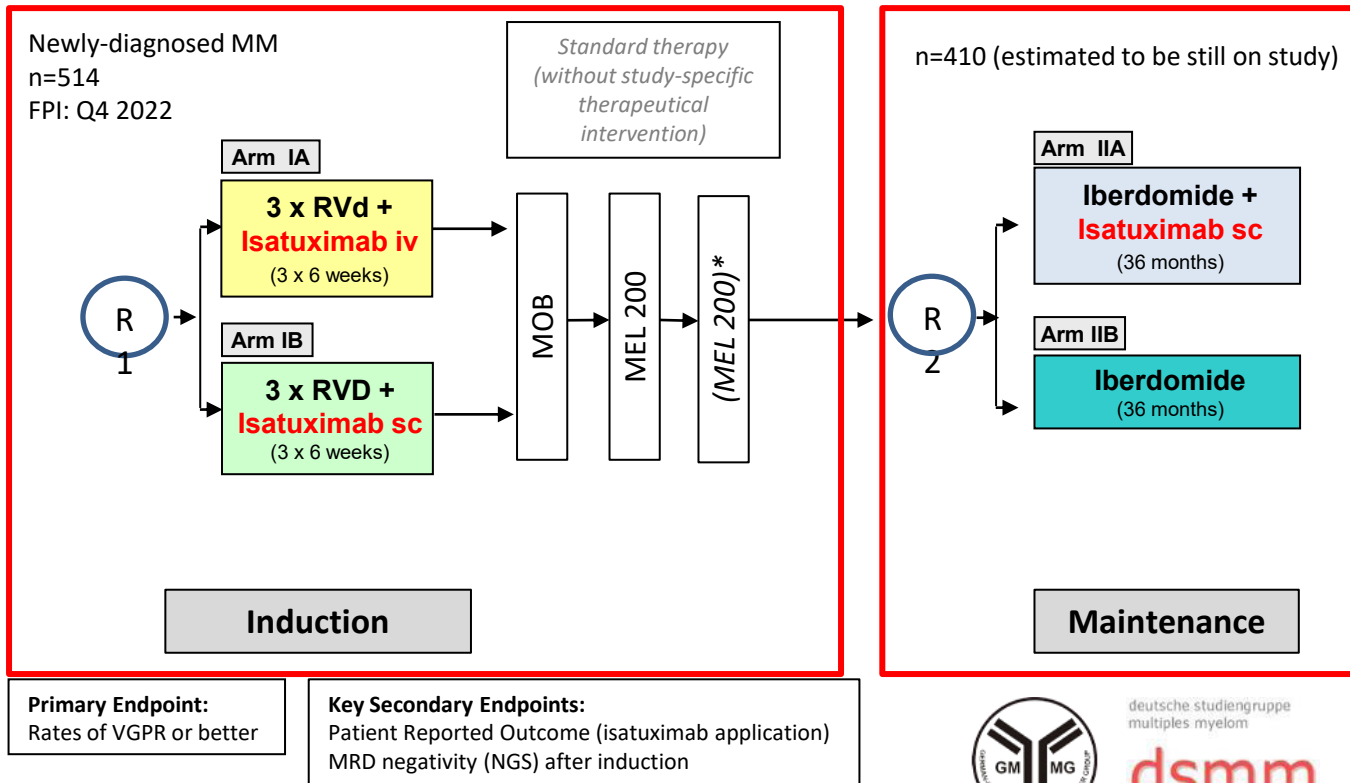
## EMN26: Conclusions

- Iberdomide maintenance results in an improvement in response over time in patients who received IMiD/PI-based induction +/- anti-CD38 antibody and autologous stem cell transplantation, which compares favorably with lenalidomide maintenance
  - Iberdomide demonstrated at least 50% improvement of response at cycle 12
  - Lenalidomide demonstrated 31% improvement of response at cycle 12 in the EMN02 trial
- Conversion to MRD-negativity during maintenance is an important outcome post-ASCT, and promising data with iberdomide were observed
- Iberdomide showed a manageable safety profile with few grade 3-4 non-hematologic adverse events
- These data support the investigation of iberdomide versus lenalidomide maintenance in the ongoing phase 3 registrational Excaliber maintenance trial



# GMMG-HD8/DSMM XIX

# GMMG-HD9/DSMM XVIII



# Kinetics and Biology of Circulating Tumor Cells (CTCs) and Measurable Residual Disease (MRD): Two Dynamic High-Risk Clones in Multiple Myeloma (MM)

651, 339

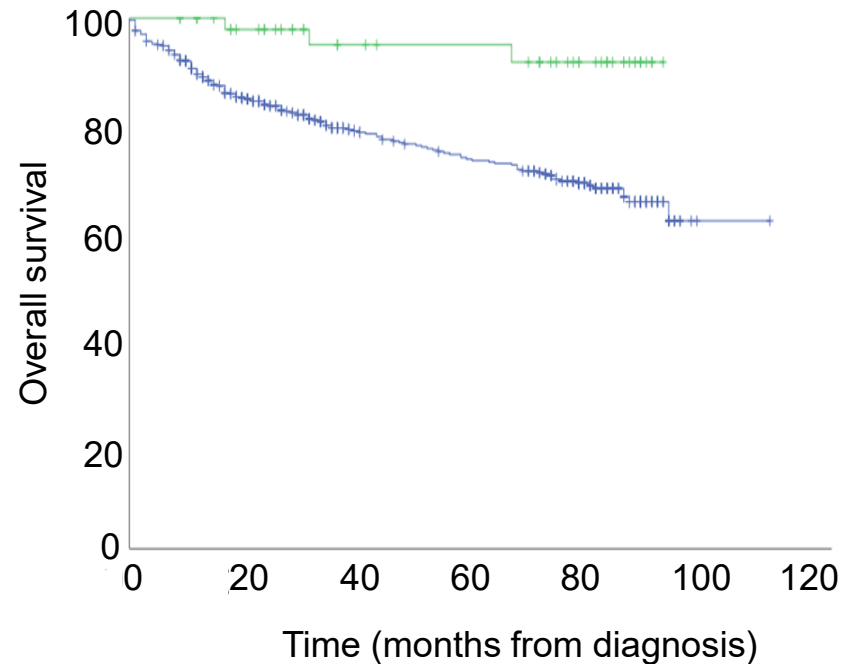
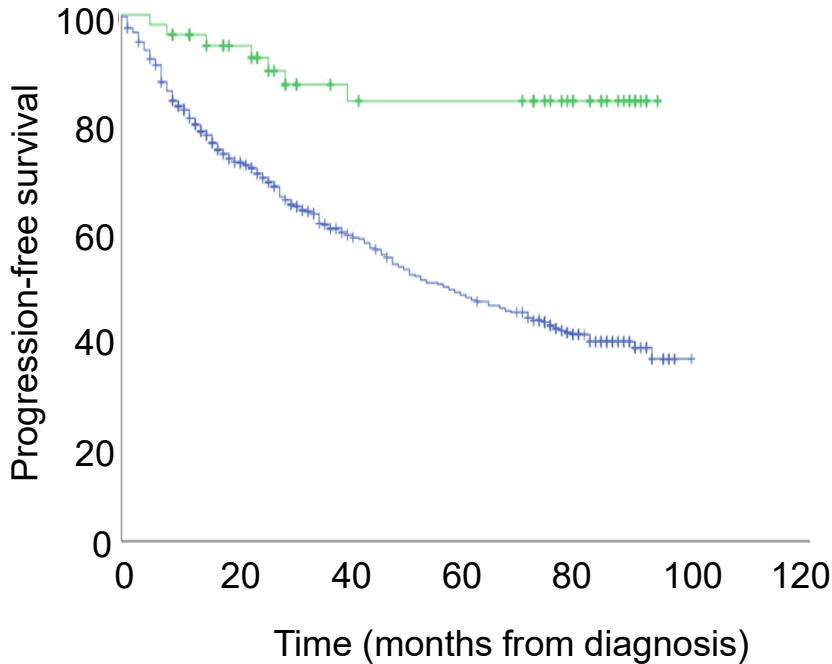
**Camila Guerrero, MSc1\***, Rosalinda Termini2\*, Juan-José Garcés, PhD3\*, Maria Jose Calasanz, PhD4\*, Rafael Ríos, MD, PhD5\*, Elena Cabezudo6\*, Laura Rosiñol, MD, PhD7\*, Bargay Joan8\*, Albert Pérez-Montaña, MD9\*, Albert Oriol Rocafiguera, MD10\*, Valentin Cabanas Perianes, MD11\*, Maria-Josefa Najera12\*, Esther Gonzalez Garcia, MD13\*, Enrique M Ocio, MD, PhD14, Anna Maria Sureda Balari, MD, PhD15, Felipe De Arriba, MD, PhD16\*, Miguel Teodoro Hernández Garcia, MD, PhD17\*, Antonio Garcia18\*, Joaquin Martinez-Lopez, MD, PhD19\*, María-Jesús Blanchard20\*, Marta Sonia Gonzalez Perez21\*, Rebeca Iglesias22\*, Alberto Orfao, MD, PhD23\*, Maria Victoria Mateos, MD, PhD24, Juan Jose Lahuerta Palacios25\*, Joan Bladé, MD, PhD26\*, Jesus San-Miguel, MD, PhD27, María T Cedena28\*, Noemi Puig, MD, PhD29 and Bruno Paiva30\*





# Absence of CTCs in NDMM is associated with longer survival

80% reduction in the risk of progression and/or death



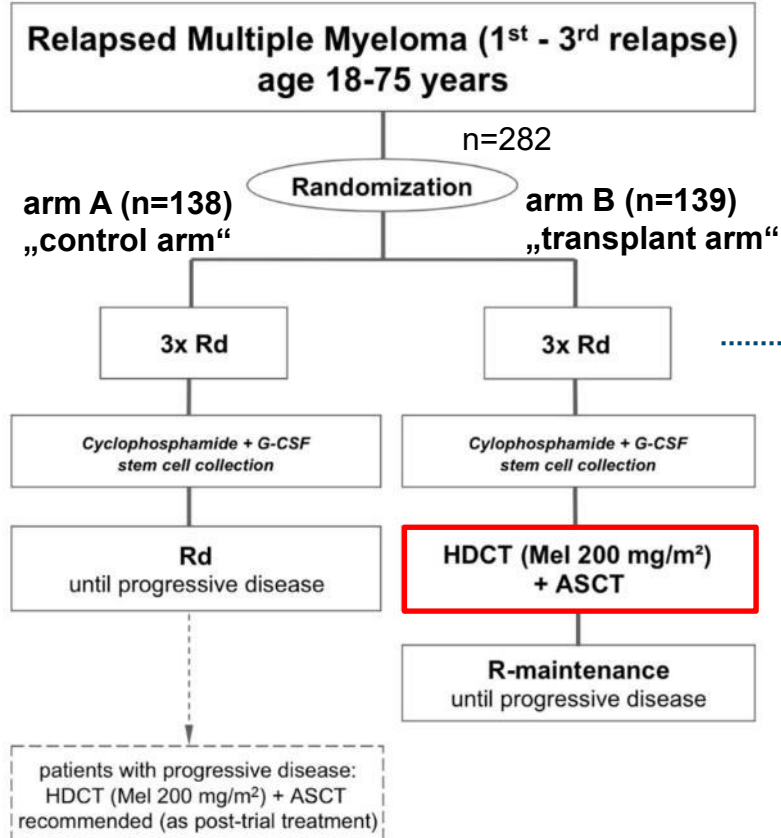
# Salvage Autologous Transplant and Lenalidomide Maintenance Versus Continuous Lenalidomide/Dexamethasone for Relapsed Multiple Myeloma: Long term follow Up results of the Randomized GMMG Phase III Multicenter Trial ReLApsE

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**Marc-Andrea Baertsch**, MD1,2, Jana Schlenzka, MD1, Thomas Hielscher<sup>3</sup>, Marc-Steffen Raab, MD1,2,4, Sandra Sauer<sup>1</sup>, MD, Maximilian Merz, MD5, Elias Karl Mai, MD1, Carsten Müller-Tidow, MD1,4, Steffen Luntz, MD6, Anna Jauch, PhD7, Peter Brossart, MD8, Martin Goerner, MD9, Stefan Klein, MD10, Bertram Glass, MD11, Peter Reimer, MD12, Ullrich Graeven, MD13, Roland Fenk, MD PhD14, Mathias Haenel, MD15, Ivana von Metzler, MD16, Hans W. Lindemann, MD17, Christof Scheid, MD18, Axel Nogai, MD19, Hans Salwender, MD20, Richard Noppeney, MD21, Britta Besemer, MD22, Katja Weisel, MD23, Hartmut Goldschmidt, MD1,4



# GMMG ReLapsE trial - Flow chart



## Rd (arm A+B)

- **Lenalidomide** 25 mg, d1-21
- **Dexamethasone** 40 mg, d1,8,15,22
- 4 week cycles

## R-maintenance (arm B)

- **Lenalidomide** 10 mg daily

Goldschmidt H\*, Baertsch MA\* et al., Leukemia, 2021



# ReLapsE - Baseline characteristics

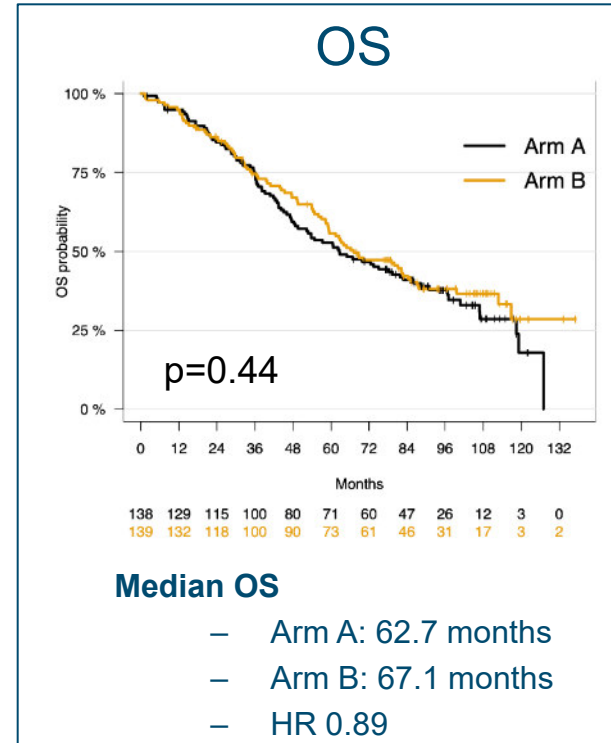
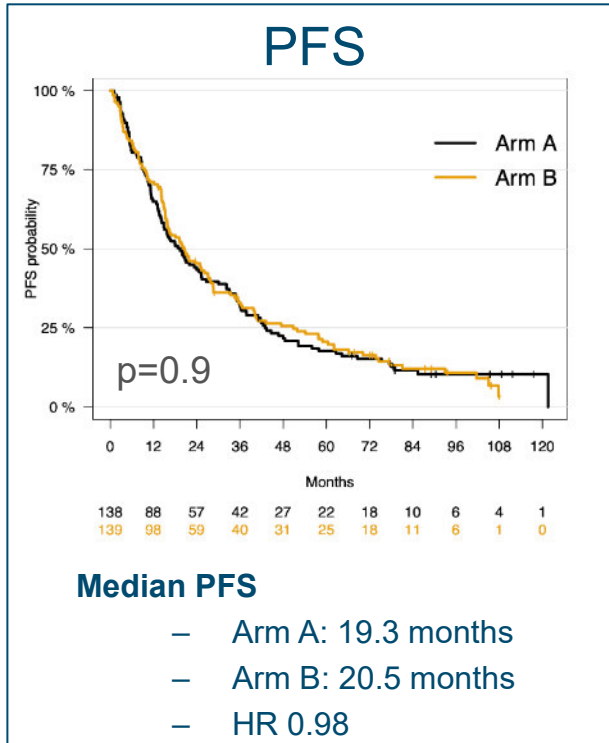


	arm A (n=138) n (%)	arm B (n=139) n (%)		arm A (n=138) n (%)	arm B (n=139) n (%)
Age [years]	62.2 (41.9; 74.5)	61.3 (29.9; 74.7)	Interval diagnosis to randomization [years]	4.1 (0.7-16.5)	3.9 (0.2-19.4)
Sex			Prior lines of therapy		
Female	54 (39)	60 (43)	1	129 (94)	131 (94)
WHO PS			2	8 (6)	5 (4)
0	105 (76)	96 (69)	3	1 (1)	3 (2)
1	32 (23)	43 (31)	Frontline HDCT/ASCT		
2	1 (1)	0	Single	130 (94)	129 (93)
ISS stage			Tandem	71 (55)	83 (64)
I	77/129 (60)	82/131 (63)	Prior therapy		
II	40/129 (31)	32/131 (24)	Bortezomib	106 (77)	107 (77)
III	12/129 (9)	17/131 (13)	Thalidomide	25 (18)	31 (22)
Cytogenetics			Lenalidomide	18 (13)	12 (9)
t(4;14)	10/99 (10)	19/94 (20)	Interferone	9 (7)	9 (6)
t(14;16)	0/97 (0)	2/90 (2)	Chemoth. only	10 (7)	14 (10)
del13q14	45/104 (43)	59/97 (61)			
del17p13	15/107 (14)	14/98 (14)			
gain1q (>3 copies)	12/105 (11)	11/97 (11)			
High risk*	31/98 (32)	39/91 (43)			

\*High risk cytogenetic aberrations: t(4;14), t(14;16), del17p13, gain1q (>3 copies)



# ReLApsE - Survival - LTFU analysis



**No survival benefit in long term follow up analysis from randomization**



# Take Home Message

- Vierer Kombinationen (CD38 Antikörper, Proteasominhibitor, Imid und Dexametason) sind der neue Standard vor und nach Hochdosistherapie
- Dauer der Therapie unklar
- MRD Knochenmark weiter gefestigt
- MRD Blut wichtiger in der Zukunft
- MassSpect Daten zeigen prognostische Bedeutung
- Auto-TPX im Rezidiv des MM Wirkung?
- Viele Präsentationen Bispez. AK und CART-Zelltherapie

# Danke!

**Addition of isatuximab to lenalidomide, bortezomib, and dexamethasone as induction therapy for newly diagnosed, transplantation-eligible patients with multiple myeloma (GMMG-HD7): part 1 of an open-label, multicentre, randomised, active-controlled, phase 3 trial**

Lancet Haematol. 2022 Nov;9(11):e810-e82

*Hartmut Goldschmidt\*, Elias K Mai\*, Uta Bertsch, Roland Fenk, Eva Nievergall, Diana Tichy, Britta Besemer, Jan Dürig, Roland Schroers, Ivana von Metzler, Mathias Hänel, Christoph Mann, Anne M Asemissen, Bernhard Heilmeier, Niels Weinhold, Stefanie Huhn, Katharina Kriegsmann, Steffen P Luntz, Tobias A W Holderried, Karolin Trautmann-Grill, Deniz Gezer, Maika Kläiber-Hakimi, Martin Müller, Cyrus Khandanpour, Wolfgang Knauf, Christof Scheid, Markus Munder, Thomas Geer, Hendrik Riesenber, Jörg Thomalla, Martin Hoffmann, Marc S Raab, Hans J Salwender, Katja C Weisel, for the German-Speaking Myeloma Multicenter Group (GMMG) HD7 investigators†*

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PD Dr. Christoph Lutz; PD Dr. Andreas Günther  
Praxis für Hämatologie und Onkologie Koblenz



# ***Danke!***

**Elotuzumab, lenalidomide, bortezomib, dexamethasone, and autologous haematopoietic stem-cell transplantation for newly diagnosed multiple myeloma (GMMG-HD6): results from a randomised, phase 3 trial**

Lancet Haematol. 2024 Feb;11(2):e101-e113

Elias K Mai\*, Hartmut Goldschmidt\*, Kaya Miah, Uta Bertsch, Britta Besemer, Mathias Hänel, Julia Krzykalla, Roland Fenk, Jana Schlenzka, Markus Munder, Jan Dürig, Igor W Blau, Stefanie Huhn, Dirk Hose, Anna Jauch, Christina Kunz, Christoph Mann, Niels Weinhold, Christof Scheid, Roland Schroers, Ivana von Metzler, Aneta Schieferdecker, **Jörg Thomalla**, Peter Reimer, Rolf Mahlberg, Ullrich Graeven, Stephan Kremers, Uwe M Martens, Christian Kunz, Manfred Hensel, Axel Benner, Andrea Seidel-Glätzer, Katja C Weisel, Marc S Raab, Hans J Salwender, for the German-speaking Myeloma Multicenter Group (GMMG) HD6 investigators†

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PD Dr. Christoph Lutz; PD Dr. Andreas Günther  
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# Danke an Prof. Dr. med. Jens Chemnitz und Team Hämatologie/Onkologie, Palliativmedizin; Klinikum Mittelrhein

GMMG Studiengruppe

	Site #	Trial site	PI	Status	Affiliation
1	8001	Aachen UK	Dr. Deniz Gezer	recruiting	GMMG
2	8008	Bad Saarow Helios	Dr. Daniel Schönbude	recruiting	GMMG
3	8021	Berlin Charité	Dr. Axel Nogai	recruiting	GMMG
4	8022	Berlin Vivantes Neukölln	Prof. Dr. Maïke De Witt	recruiting	GMMG
5	8026	Bielefeld Praxis	Dr. Hendrik Riesenberger	initiated	GMMG
6	8023	Bochum UK	Prof. Dr. Schroers	recruiting	GMMG
7	8031	Bonn Johanner	Prof. Dr. Yon-Dschun Ko	recruiting	GMMG
8	8028	Bonn UK	Dr. Tobias Holderried	recruiting	GMMG
9	8033	Chemnitz	PD Dr. Matthias Hänel	recruiting	GMMG
10	8035	Cottbus Carl-Thiem-Klinikum	PD Dr. Martin Schmidt	recruiting	GMMG
11	8036	Darmstadt Klinikum	Prof. Dr. Helga Bernhard	recruiting	GMMG
12	8041	Duisburg Helios St. Johannes	Dr. Michael Heinsch	recruiting	GMMG
13	8040	Düsseldorf Marien-Hospital	Dr. Maika Klaißer-Hakimi	recruiting	GMMG
14	8067	Düsseldorf UK	Prof. Dr. Roland Fenk	recruiting	GMMG
15	8042	Eschweiler St. Antonius Hospital	PD Dr. Peter Staib	recruiting	GMMG
16	8034	Essen UK	Dr. Christine Hanoun	recruiting	GMMG
17	8038	Essen-Werden Evang. Kliniken	Prof. Dr. Peter Reimer	recruiting	GMMG
18	8044	Frankfurt am Main Praxis Knauf	Prof. Dr. Wolfgang Knauf	recruiting	GMMG
19	8045	Frankfurt UK	Dr. Ivana von Metzler	initiated	GMMG
20	8047	Gießen UK	Dr. Tobias Arnold	initiated	GMMG
21	8054	Hagen	Prof. Dr. Doris Kraemer	activated	GMMG
22	8046	Hamburg Altona Asklepios	Dr. Hans-Jürgen Salwender	activated	GMMG
23	8068	Hamburg UKE	Prof. Dr. med. Katja Weisel	recruiting	GMMG
24	8052	Heidelberg Praxis Fuxius/Debatin	Dr. med. Stefan Fuxius	recruiting	GMMG
25	8051	Heidelberg UK	Prof. Dr. Goldschmidt	recruiting	GMMG
26	8057	Heilbronn SLK Kliniken	Prof. Martens	recruiting	GMMG
27	8053	Homburg	Dr. Jörg Bittenbring	recruiting	GMMG
28	8060	Kaiserslautern Westfalz Klinikum	Prof. Dr. Gerhard Held	recruiting	GMMG
30	8063	Köln UK	Prof. Dr. Christoph Scheid	recruiting	GMMG
31	8066	Ludwigshafen Klinikum	Dr. Martin Hoffmann	activated	GMMG
32	8077	Mainz UK	Prof. Markus Munder	activated	GMMG
33	8074	Mannheim Onkol.	Prof. Dr. Manfred Hensel	activated	GMMG
34	8073	Marburg Philipps-Universität	Dr. Christoph Mann	recruiting	GMMG
35	8081	Meschede	Dr. Mohammed Wattad	activated	GMMG
36	8079	Mönchengladbach	Prof. Dr. Ullrich Graeven	recruiting	GMMG
37	8082	Osnabrück	PD Dr. Martin Kropff	initiated	GMMG
38	8083	Paderborn	Dr. Tobias Gaska	recruiting	GMMG
39	8084	Regensburg Barmherzige Brüder	Dr. Bernhard Heilmeier	activated	GMMG
40	8088	Lebach	PD Dr. Stefan Bauer	activated	GMMG
41	8087	Saarbrücken	PD Dr. Topaly	recruiting	GMMG
42	8086	Schwäbisch Hall Diakonie	Dr. Thomas Geer	activated	GMMG
43	8085	Siegburg ZAHO	Dr. Stefan Fronhoffs	activated	GMMG
44	8089	Speyer Onkol. Schwerpunktpraxis	Dr. Lars Scheuer	activated	GMMG
45	8091	Trier Mutterhaus	Dr. Rolf Mahlberg	recruiting	GMMG
46	8092	Tübingen UK	Dr. Britta Besemer	recruiting	GMMG
47	8096	Villingen-Schwenningen SBK	Prof. Dr. Paul La Rosée	activated	GMMG
48	8094	Wiesbaden	Dr. Wolfgang Blau	recruiting	GMMG
49	8099	Wuppertal	Dr. Blasius Liss	recruiting	GMMG

DSMM Studiengruppe inkl. AGMT-Zentren (Österreich)

	Site #	Trial site	PI	Status	Affiliation
	8101	Augsburg	Prof. Dr. Björn Hackanson	recruiting	DSMM
	8104	Bayreuth	Dr. Carla Dorn	activated	DSMM
	8105	Berlin-Buch	Dr. Snjezana Janjetovic	recruiting	DSMM
	8106	Berlin Spandau	Dr. Annegret Kunitz	recruiting	DSMM
	8108	Bremen	Dr. Matthias Bormann	recruiting	DSMM
	8107	Bielefeld Klinikum	Prof. Dr. Florian Weißinger	recruiting	DSMM
	8102	Dessau	Prof. Dr. Bernhard Gehre	recruiting	DSMM
	8109	Dortmund	Dr. Ralf Meyer	activated	DSMM
	8110	Dresden UK	Dr. Katrin Trautmann-Grill	activated	DSMM
	8111	Flensburg Malteser	Dr. Petra Drewniok	activated	DSMM
	8112	Freiburg	Prof. Dr. Ralph Wäsch	recruiting	DSMM
	8113	Göttingen	Dr. Wolfram Jung	recruiting	DSMM
	8114	Greifswald	Dr. Annamaria Brioli	recruiting	DSMM
	8115	Halle-Wittenberg	Dr. Franziska Brunner	recruiting	DSMM
	8117	Jena UK	Dr. Olaposi Yomade	recruiting	DSMM
	8118	Karlsruhe	Dr. Lukas Kundgen	recruiting	DSMM
	8119	Kempten	Prof. Dr. Christian Langer	recruiting	DSMM
	8120	Kiel UK	Dr. Natalie Schub	recruiting	DSMM
	8121	Koblenz GK	Dr. Christian Breitbarth-Girmscheid	recruiting	DSMM
	8122	Leipzig UK	Dr. Merz	recruiting	DSMM
	8123	Lübeck UK	Prof. Dr. Cyrus Khanandpour	initiated	DSMM
	8124	Magdeburg	Dr. Denise Wolleschak	recruiting	DSMM
	8125	Mannheim UK	Dr. Stefan Klein	recruiting	DSMM
	8128	München Rotkreuz	Prof. Dr. med. Marcus Hentrich	recruiting	DSMM
	8129	TUM München	Prof. Dr. Florian Bassermann	recruiting	DSMM
	8130	Münster	Dr. Evgenii Shumilov	recruiting	DSMM
	8131	Mutlangen	Prof. Dr. med. Holger Hebart	activated	DSMM
	8132	Nürnberg	Dr. Knut Wendelin	recruiting	DSMM
	8133	Oldenburg	Dr. Christoph Kimmich	recruiting	DSMM
	8135	Regensburg UK	Dr. Matthias Grube	recruiting	DSMM
	8138	Stuttgart Robert Bosch KH	PD Dr. Nicola Giesen	recruiting	DSMM
	8139	Stuttgart Diakonie	Prof. Dr. Jochen Greiner	recruiting	DSMM
	8141	Ulm UK	Dr. Miriam Kull	recruiting	DSMM
	8142	Würzburg UK	Prof. Dr. Kortüm	recruiting	DSMM
	8140	Stuttgart Katharienhospital	Dr. Ulrike Krohn	recruiting	DSMM
	8150	Graz (Austria)	Prof. Dr. Sigfried Sormann	recruiting	DSMM
	8151	Krems (Austria)	PD Dr. Klaus Podar	recruiting	DSMM
	8152	Linz Ordensklinikum	Dr. Irene Strassl	recruiting	DSMM
	8153	Linz Kepler UK (Austria)	Univ.-Prof. Dr. Clemens Schmitt	recruiting	DSMM
	8154	Rankweil Feldkirch (Austria)	Dr. Bernd Hartmann	activated	DSMM
	8155	Salzburg (Austria)	Prim. Univ.-Prof. Dr. Richard Greil	recruiting	DSMM
	8156	St. Poelten (Austria)	Dr. Petra Pichler	recruiting	DSMM
	8157	Steyr (Austria)	Dr. Hanns Hauser	recruiting	DSMM
	8158	Wels-Grieskirchen (Austria)	Dr. Sonja Heibl	recruiting	DSMM
	8160	Wien Ottakring (Austria)	Dr. Martin Schreder	recruiting	DSMM



# Danke!

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