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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Presented by M-S Raab at the Annual Meeting of the German, Austrian and Swiss Associations of Hematology and Medical Oncology (DGHO); October 11–14, 2024; Basel, Switzerland

Disclosures of Conflicts of Interest

M-SR has served in a consulting/advisory role for and has received honoraria from AbbVie, Amgen, BMS, GSK, Janssen, and Sanofi; has received research funding from BMS, Heidelberg Pharma, Janssen, and Sanofi; and is currently employed at Heidelberg University Hospital. **JH** has received payment or honoraria from Amgen, Beigene, ESMO Florida, and Targeted Oncology; has served in a consulting/advisory role for Angitia, Axxess Network, GSK, Janssen, OncLive, Oncopeptides, Prothena, Sanofi, and Skyline; has received research funding from GSK; and has served on a DSMB for Janssen. **ADC** has served in a consulting/advisory role for AbbVie, Arcellx, BMS/Celgene, Genentech/Roche, GSK, Ichnos, Janssen, and Pfizer; has received research funding from Genentech/Roche, GSK, Janssen, and Novartis; and has received patents & royalties from Novartis. **MA** is an equity holder in GenCART, Inc. **MD** served as a consultant or advisor for Amgen, BMS, GSK, Janssen, Sanofi, Stemline Therapeutics, and Takeda. **TK** has nothing to disclose. **WR** served as a consultant or advisor for AbbVie, BMS, and Takeda; and received honoraria from Amgen, BMS, Janssen, Sanofi. **HE** served as a consultant or advisor for Amgen, BMS, Celgene, GSK, Janssen, and Sanofi; received honoraria from Amgen, BMS, Celgene, GSK, Janssen, and Sanofi; and received research funding from Amgen, BMS, Celgene, GSK, Janssen, and Sanofi. **HG** served as a consultant or advisor for Adaptive Technologies, Amgen, BMS, Celgene, Janssen-Cilag, Sanofi, and Takeda; received honoraria from Amgen, BMS, Celgene, Chugai Pharma, GSK, Janssen-Cilag, Novartis, and Sanofi; received research funding from Amgen, BMS, Celgene, Chugai Pharma Europe, Incyte, Janssen, Molecular Partners, MSD, Mundipharma, Novartis, and Takeda; received travel and accommodation funding from Janssen-Cilag and Sanofi; and received other financial reimbursements from Amgen, Celgene, BMS, Chugai Pharma Europe, Janssen, and Sanofi. **KW** served as a consultant or advisor to Adaptive Biotechnologies, Amgen, BMS, Celgene, GSK, Janssen-Cilag, Karyopharm Therapeutics, Menarini, Oncopeptides, Roche, Sanofi, and Takeda; received travel and accommodation funding from Amgen, BMS, Celgene, GSK, Janssen-Cilag, Menarini, and Takeda; received honoraria from AbbVie, Adaptive Biotechnologies, Amgen, BMS, Celgene, GSK, Janssen-Cilag, Karyopharm Therapeutics, Menarini, Novartis, Oncopeptides, Pfizer, Roche, Sanofi, Stemline Therapeutics, and Takeda; received honoraria paid to their institution from Janssen; and received research funding paid to their institution from AbbVie, Amgen, BMS, Celgene, GSK, Janssen-Cilag, and Sanofi. **CS** has nothing to disclose. **SA** has nothing to disclose. **PS** received honoraria from Amgen, BMS, Celgene, Janssen, Karyopharm, Pfizer, and Takeda; and received research funding from Amgen, BMS, Celgene, Janssen, Karyopharm, SkylineDx, and Takeda. **SZ** served as a consultant or advisor for Celgene and Janssen, Takeda; and received research funding from Celgene, Janssen, and Takeda. **JMS** is employed by and holds patents/royalties from Janssen. **KCDB** is currently employed by Janssen. **CCJ** was an employee/holds stock and other ownership interests in Janssen Research & Development. **PV**, **HV**, **CC**, **DM, TY**, **PM** and **TR** are currently employed by and hold equity in Janssen. **QS** is currently employed by and holds equity in Johnson & Johnson. **MA**, **OCF** and **DG** are employed by and hold equity in Legend Biotech USA Inc. **YCC** served as a consultant or advisor to Amgen, GSK, and Janssen; received honoraria from BMS, Janssen, and Roche; served on the speakers' bureau for AbbVie and GSK; received research funding from Takeda; and received travel and accommodation funding from Sanofi Aventis GmbH. **NWCJvdD** served as a consultant or advisor to AbbVie, Adaptive Biotechnologies, Amgen, Bayer, BMS, Celgene, Janssen, Novartis, Pfizer, Roche, SERVIER, and Takeda; and received research funding from Amgen, BMS, Celgene, Cellectis, Janssen, and Novartis.

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[1,2]
  - Basis for approval in patients with RRMM with ≥3 and ≥4 prior LOT in Europe and the US, respectively[3,4]
- CARTITUDE-2 is a multicohort study of cilta-cel use in patients as early as after 1 prior LOT[5-7]
  - 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% ≥CR) as previously reported[5]

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

ORR, 100% (90% ≥CR) as previously reported[6]

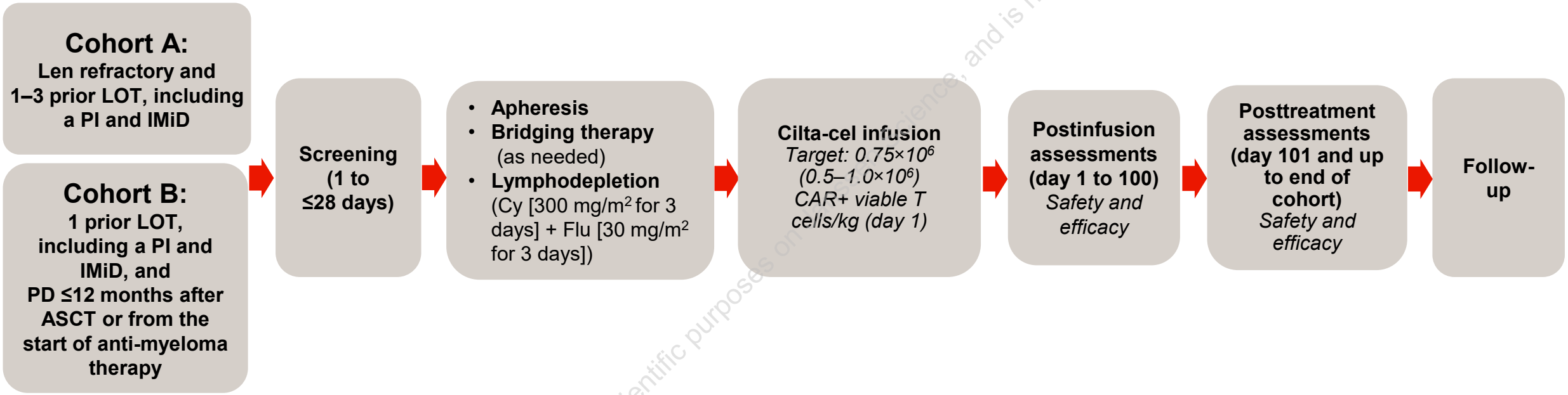
Objective: To report updated efficacy and safety data from CARTITUDE-2 cohorts A and B after a median follow-up of ~29 months

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.

Presented by M-S Raab at the Annual Meeting of the German, Austrian and Swiss Associations of Hematology and Medical Oncology (DGHO); October 11–14, 2024; Basel, Switzerland

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



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

[a]Assessed per IMWG criteria. [b]Assessed per CTCAE version 5.0. [c]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; NGF, next-generation flow; 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.

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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[a] ≥60%, n (%)	3 (15.0)	4 (21.1)
Extramedullary plasmacytomas, n (%)	3 (15.0)	3 (15.8)
Cytogenetic high risk,[b] n (%)	7 (35.0)[c]	3 (15.8)[d]
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,[e] n (%)		
Autologous	17 (85.0)	15 (78.9)
Exposure status, n (%)		
Triple-class[f]	13 (65.0)	4 (21.1)
Penta-drug exposed[g]	4 (20.0)	0
Refractory status, n (%)		
Triple-class[f]	8 (40.0)	3 (15.8)
Penta-drug refractory[g]	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[h]–35.6) in cohort A and 27.9 months (range, 5.2[h]–32.1) in cohort B

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

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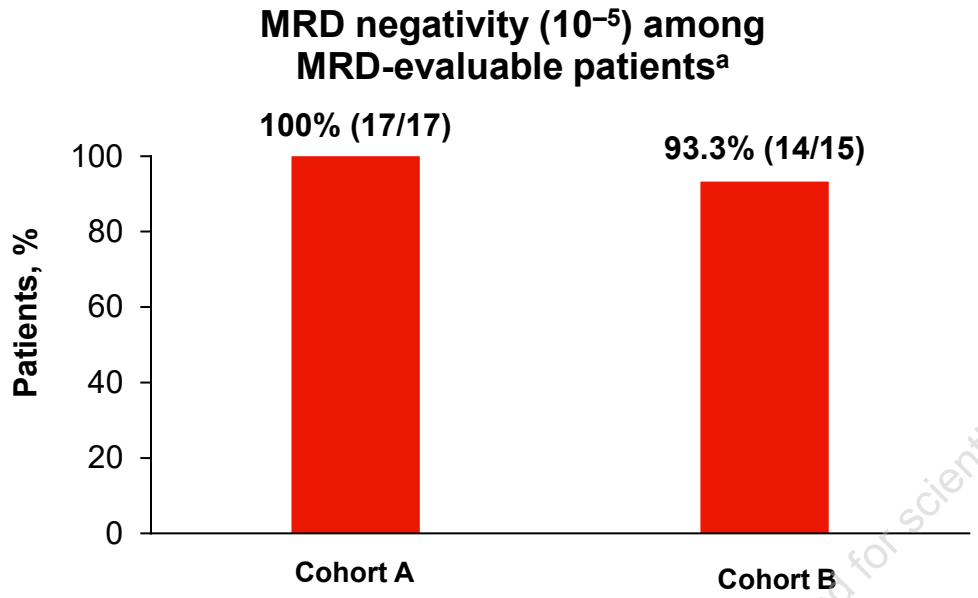
CARTITUDE-2 Cohorts A & B: MRD Negativity (Primary Endpoint)

(~29-month median follow-up)

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



Sustained MRD negativity[b]	Cohort A	Cohort B
Patients evaluable for sustained MRD negativity ≥6 mo[c]	**n=11**	**n=13**
Sustained MRD negativity (10^{-5}) ≥6 mo,[d] n (%)	8 (72.7)	10 (76.9)
Patients evaluable for sustained MRD negativity ≥12 mo[e]	**n=14**	**n=13**
Sustained MRD negativity (10^{-5}) ≥12 mo,[f] 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.

[a]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). [b]Post hoc analysis. [c]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. [d]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 ≥6 months as denominator. [e]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. [f]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 ≥12 months as denominator.
CR, complete response; mo, months; MRD, minimal residual disease; NGF, next-generation flow; NGS, next-generation sequencing; sCR, stringent CR.

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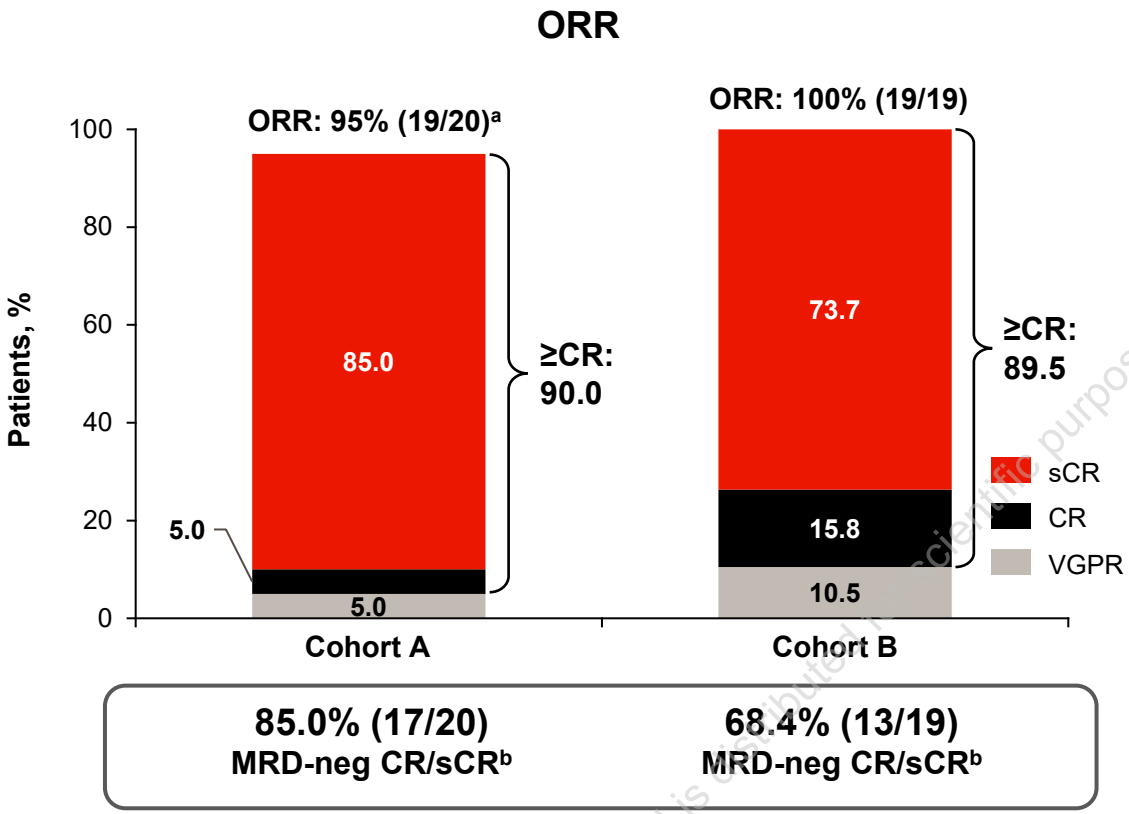
CARTITUDE-2 Cohorts A & B: Response (Secondary Endpoints)

(~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,[c] 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)
Duration of response		
24-mo DOR rate, % (95% CI)	73.3 (47.2–87.9)	70.5 (42.5–86.7)

[a]1 patient had a minimal response. [b]Only MRD assessments (10^{-5} testing threshold) within 3 months of achieving CR/sCR until death/progression/subsequent therapy (exclusive) are considered. [c]≥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.

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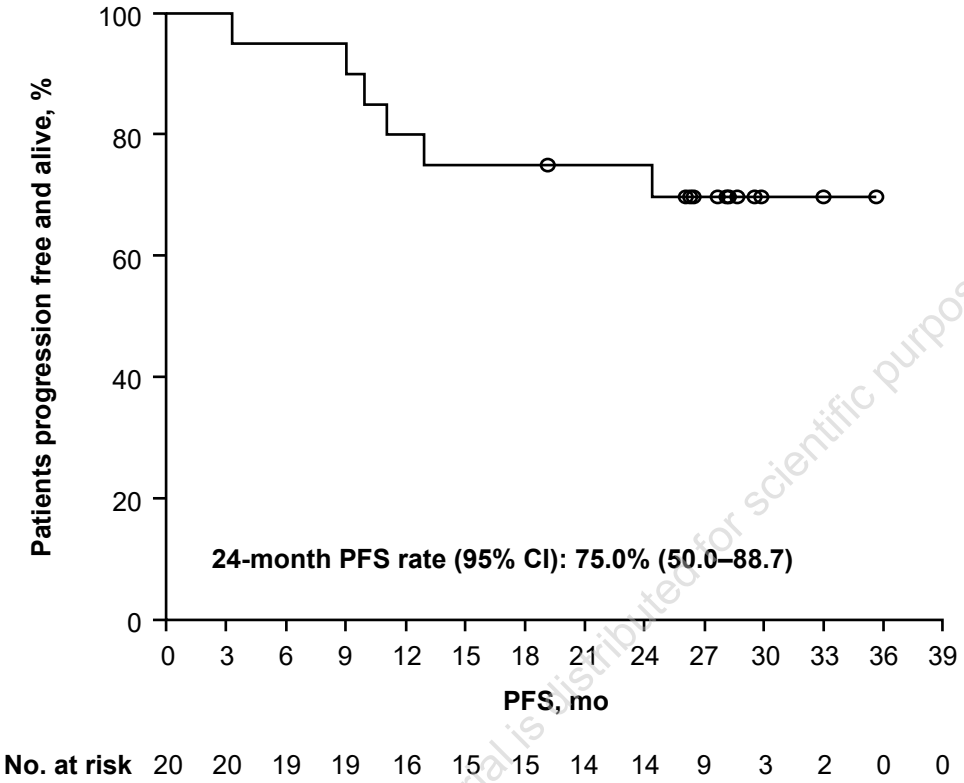
CARTITUDE-2 Cohort A: PFS and OS (Exploratory Endpoints)

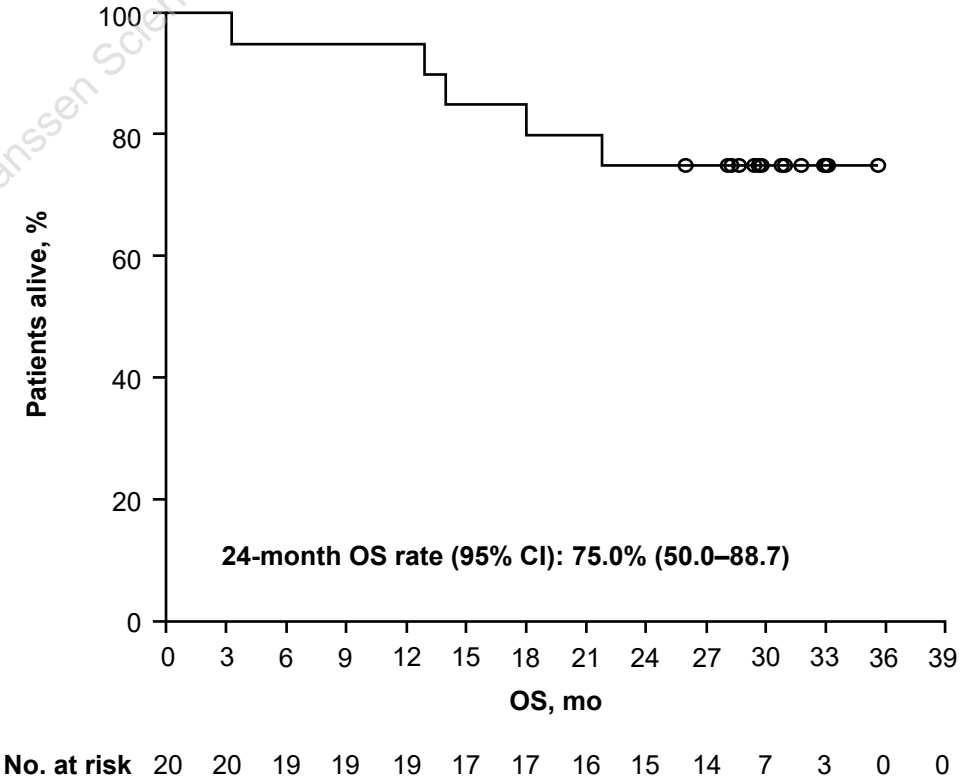
(~29-month median follow-up)

PFS and OS maintained with additional follow-up

Cohort A, PFS



Cohort A, OS



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

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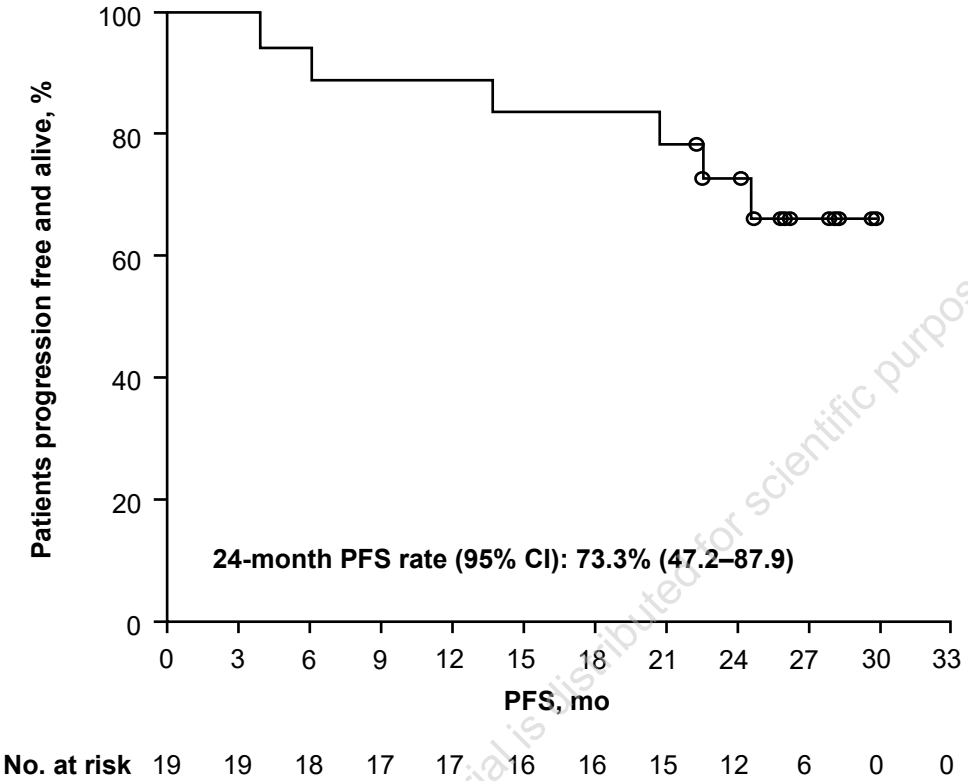
CARTITUDE-2 Cohort B: PFS and OS (Exploratory Endpoints)

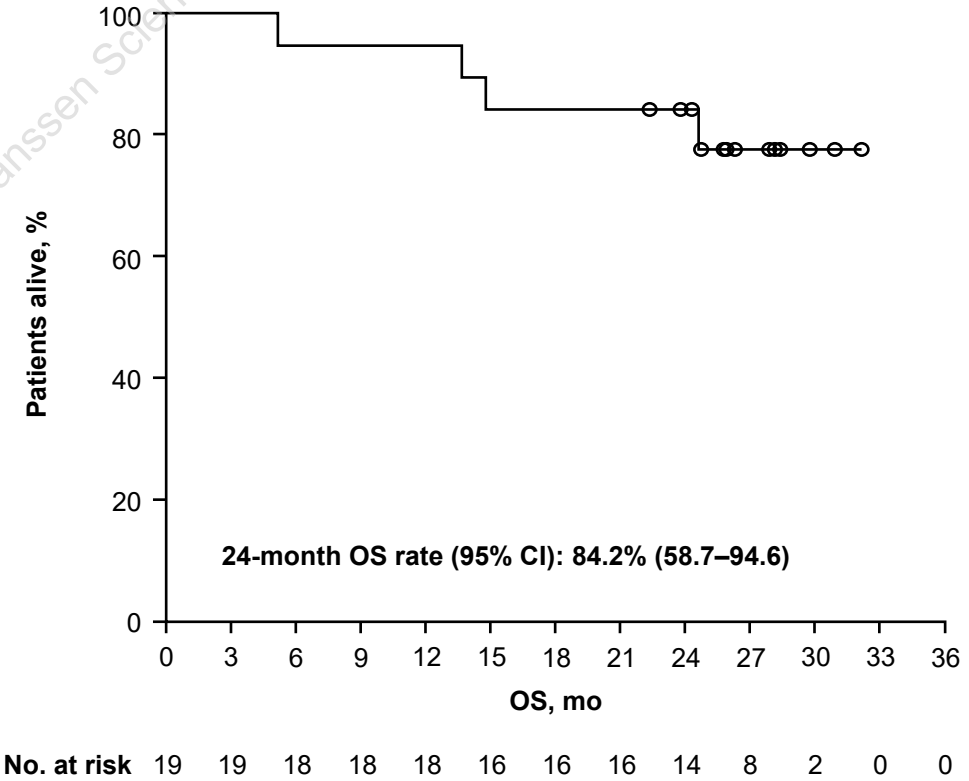
(~29-month median follow-up)

PFS and OS maintained with additional follow-up

Cohort B, PFS



Cohort B, OS



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

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

Cohort B

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

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)	–
Hematologic				
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)

[a]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). [b]Not treatment related. [c]1 new death on day 666 since last data cut-off. [d]Patient also had an AE of sepsis in addition to COVID-19 pneumonia. [e]Treatment related. [f]No change since previous data cut-off. [g]New event since last data cut-off.
AE, adverse event; cilta-cel, ciltacabtagene autoleucel; PD, progressive disease; TEAE, treatment-emergent AE.

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CARTITUDE-2 Cohorts A & B: CRS and CAR-T Cell Neurotoxicity (Secondary Endpoint)

(~29-month median follow-up)

CRS and CAR-T cell neurotoxicity were low grade in severity

AEs, n (%)	Cohort A (N=20)				
	Any Grade	Grade 3/4	Median time to onset, days	Median duration, days	Resolved, n
CRS	19 (95.0)	2 (10.0)	7	3	19
CAR-T cell neurotoxicity	6 (30.0)	1 (5.0)	–	–	–
ICANS	3 (15.0)	0	8	3	3
Other	3[a] (15.0)	1 (5.0)	30	80	2
MNT	0	0	–	–	–

AEs, n (%)	Cohort B (N=19)				
	Any Grade	Grade 3/4	Median time to onset, days	Median duration, days	Resolved, n
CRS	16 (84.2)	1 (5.3)	8	4	16
CAR-T cell neurotoxicity	6 (31.6)	1 (5.3)	–	–	–
ICANS	1 (5.3)	0	11	4	1
Other[b]	5[c] (26.3)	1 (5.3)	22	128	3
MNT	1[d] (5.3)	1 (5.3)	38	–[e]	–[e]

- In both cohorts, most cases of CRS and CAR-T cell neurotoxicity resolved
  - **Cohort A:** 19/19 CRS cases, 3/3 ICANS cases, and 2/3 other neurotoxicity cases resolved
  - **Cohort B:** 16/16 CRS cases, 1/1 ICANS case, and 3/5 other neurotoxicity cases resolved

[a]1 case each of peripheral sensorimotor neuropathy (recovering/resolving), anosmia (resolved), and facial paralysis (resolved). [b]1 new other neurotoxicity of grade 2 sensory loss (which resolved) since the last data cut-off. [c]1 case each of MNT (not resolved), hypoesthesia (not resolved), sensory loss (resolved), facial paralysis (resolved), and personality change (resolved). [d]Patient had associated risk factors for MNTs—high baseline tumor burden (95% plasma cells in BM biopsy at LD [M-protein from 5.0 g/dL at screening to 6.1 g/dL at LD chemotherapy]), worsening tumor burden despite bridging therapy, grade 4 CRS, and high CAR-T cell expansion and persistence. [e]Not recovered/resolved as of this data cut-off, patient died due to cardiac arrest on day 749 post. cilta-cel. AE, adverse event; BM, bone marrow; CAR, chimeric antigen receptor; cilta-cel, ciltacabtagene autoleucel; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; LD, lymphodepletion; MNT, movement and neurocognitive treatment-emergent AE.

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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 ≥24 months
- 24-month PFS and OS rates were both 75%
- No new or unexpected CAR-T–related safety signals were observed

Cohort B: Progressed ≤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 ≥24 months
- 24-month PFS and OS rates were 73% and 84%, respectively
- No new or unexpected CAR-T–related safety signals were observed

- A similar patient population to CARTITUDE-2 Cohort A is being evaluated in the phase 3 CARTITUDE-4 trial[1]

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.

Presented by M-S Raab at the Annual Meeting of the German, Austrian and Swiss Associations of Hematology and Medical Oncology (DGHO); October 11–14, 2024; Basel, Switzerland

Acknowledgments

- The authors, Janssen, and Legend Biotech USA Inc. thank the patients who participated in this study, the staff members at the study sites, the data and safety monitoring committee, and the staff members involved in data collection and analyses
- This study was funded by Janssen Research & Development, LLC, and Legend Biotech USA Inc.
- Medical writing support was provided by Niraja Suresh, PhD, of Eloquent Scientific Solutions, and funded by Janssen Global Services, LLC

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Presented by M-S Raab at the Annual Meeting of the German, Austrian and Swiss Associations of Hematology and Medical Oncology (DGHO); October 11–14, 2024; Basel, Switzerland

https://www.congresshub.com/Oncology/DGHO2024/Cilta-cel/Raab

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