Ciltacabtagene Autoleucel (Cilta-cel) vs Standard of Care (SOC) in Patients (Pts) with Relapsed/Refractory Multiple Myeloma (MM): CARTITUDE-4 Survival Subgroup Analyses

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Key Takeaway



Cilta-cel improved PFS and OS vs SOC across subgroups in CARTITUDE-4, including patients with standard- and high-risk cytogenetics, EMD, and 1 pLOT and beyond

Conclusions



ITT analysis showed that cilta-cel improved PFS and OS vs SOC across subgroups, including patients with EMD and 1 pLOT and beyond



Compared with SOC, cilta-cel improved PFS and OS in patients with high-risk cytogenetics, suggesting it may overcome the poor prognosis associated with these high-risk features



These data continue to support a positive benefit-risk ratio for cilta-cel in patients with lenalidomide-refractory MM as early as after first relapse



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Disclosures

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Introducti

Results

Study population

Cilta-cel vs SOC by cytogenetic risk

and high-risk cytogenetics

- In CARTITUDE-4 (NCT04181827), a single cilta-cel infusion significantly prolonged progression-free survival (PFS) and overall survival (OS) in patients with lenalidomide-refractory MM after 1–3 prior lines of therapy (pLOT)¹
- At median follow up of 33.6 months, PFS (hazard ratio [HR] weighted, 0.29 [95% CI, 0.22–0.39]) and OS (HR, 0.55 [0.39–0.79];
 P=0.0009) were significantly improved vs SOC¹
- Overall minimal residual disease (MRD)-negative complete response (CR) or better rates (82.1% vs 25.2%) as well as sustained (≥12 months) MRD-negative ≥CR (51.7% vs 9.7%) rates in evaluable patients were higher in the cilta-cel arm vs SOC²
- Here, we report PFS and OS from subgroups of patients with standard-/high-risk cytogenetics, with/without extramedullary disease (EMD), and with 1, 2, or 3 pLOT

As of May 1, 2024, the median follow-up was 33.6 months (range,

Cilta-cel consistently improved PFS and OS compared with SOC in

High-risk cytogenetics was defined as del(17p), t(4;14), t(14;16),

patients with standard risk and high risk (Figures 2 and 3)

or gain/amp(1q) by fluorescence in situ hybridization

High risk, cilta-cel

0 3 6 9 12 15 18 21 24 27 30 33 36 39 42 45

Progression-free survival months

0 3 6 9 12 15 18 21 24 27 30 33 36 39 42 45

69 65 61 59 57 57 56 56 56 55 52 35 13 5 2 0

High risk, SOC 132 130 126 116 110 103 96 91 84 81 75 38 14 6 0 0

High risk cilta-cel 123 121 115 111 105 103 102 98 95 93 83 50 23 14 5 0

Standard risk, SOC 70 69 62 61 57 55 54 52 49 48 48 29 18 5 3 0

High risk, SOC 132 111 79 65 52 42 37 31 28 23 20 7 3 0 0

High risk, cilta-cel 123 106 102 96 92 87 84 76 73 70 55 31 14 7 2 0

Standard risk, SOC 70 58 50 47 41 36 35 32 32 29 27 18 9 1 1 0

Standard risk, cilta-cel 69 59 58 57 53 51 49 49 49 49 46 27 9 2 1 0

-▲- Standard risk, cilta-cel

High risk, SOC

Standard risk, SOC

- High risk, cilta-cel

- High risk, SOC

– 📥 - Standard risk, cilta-ce

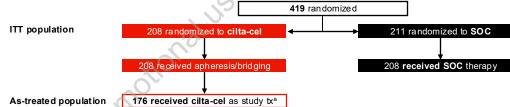
Figure 2: Kaplan-Meier analysis of patients with standard-risk

Method

Treatment and data analysis

- CARTITUDE-4 study design has been described previously³
- Patients (n=208) randomized to the cilta-cel arm underwent apheresis, bridging treatment, lymphodepletion, and then a single cilta-cel infusion (n=176; Figure 1)
- Bridging treatment consisted of either:
- Pomalidomide, bortezomib, and dexamethasone (PVd) or
- Daratumumab, pomalidomide, and dexamethasone (DPd)

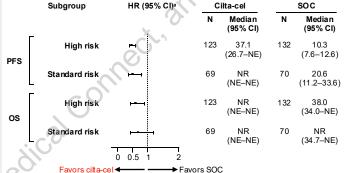
Figure 1: Randomization and treatment



*32 patients did not receive cita-cel as study treatment (r=30 due to disease progression; n=2 due to death during bridging therapy/lymphodepletion), of which 20 received cita-cel as subsequent LOT, ITT, intent to treat; LOT, line of therapy; bx, treatment.

- Patients (n=211) randomized to the SOC arm received physician's choice of PVd or DPd until disease progression (n=208)
- PFS was assessed using a validated computerized algorithm; HR was analyzed using unweighted Cox proportional hazards model for the ITT analysis set

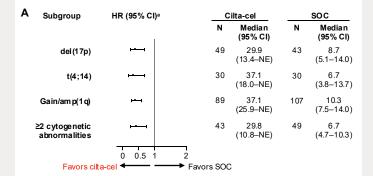
Figure 3: PFS and OS in patients with high-risk and standard-risk cytogenetics

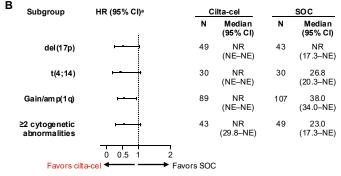


ITT population, median PFS and OS are shown in months. PFS was estimated by the Kaplan-Meier method. *Hazard ratio and 85% Cl from a Cox proportional hazards model with treatment as the sole explanatory variab. NE, not estimable, NR, not reached.

 Cilta-cel improved PFS and OS compared with SOC in patients with del(17p), t(4;14), gain/amp(1q), and ≥2 cytogenetic abnormalities from the ITT population (Figure 4)

Figure 4: (A) PFS and (B) OS in cytogenetic high-risk MM



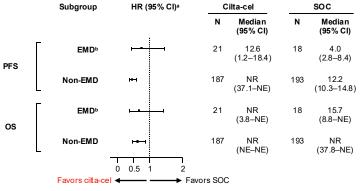


Median PFS and OS are shown in months. PFS was estimated by the Kaplan-Meier method. *Hazard ratio and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable. The subgroup (n=7) size for (*14;16) was too small to derive reliable statistics.

Cilta-cel for patients with EMD

- Cilta-cel improved median PFS and OS compared with SOC in patients with EMD (Figure 5)
- Of 21 patients with EMD randomized to cilta-cel, 13 received cilta-cel as study treatment
- In the as-treated population with EMD (N=13), median PFS (95% CI) was 18.4 (12.6–NE) and median OS (95% CI) was NR (NE–NE)

Figure 5: PFS and OS in patients with EMD and non-EMD

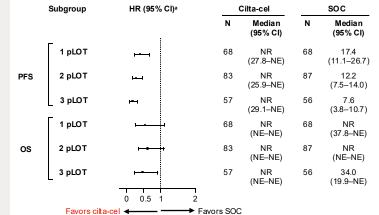


ITT population, median PFS and OS are shown in months. PFS was estimated by the Kaplan-Meier method. *Hazard ratik and 95% C1 from a Cox proportional hazards model with treatment as the sole explanatory variable. *Extramedullary disease dendes soft issue plasmacytema that was not configuous with bone.

Cilta-cel for patients with 1-3 pLOT

 Cilta-cel significantly improved PFS and OS compared with SOC in patients with MM in each subgroup of pLOT (Figure 6)

Figure 6: PFS and OS in patients with pLOT



ITT population, median PFS and OS are shown in months. PFS was estimated by the Kaplan-Meier method.

*Hazard ratio and 95% Cl from a Cox proportional hazards model with treatment as the sole explanatory variable.

References

Retreences

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Multiple Myeloma

