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P1138 FIVE-YEAR EFFICACY AND SAFETY OF TAFASITAMAB IN PATIENTS WITH RELAPSED OR REFRACTORY DLBCL: FINAL RESULTS FROM THE PHASE II L-MIND STUDY

Topic: 19. Aggressive Non-Hodgkin lymphoma - Clinical

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Background:

Tafasitamab, an anti-CD19 immunotherapy that enhances antibody-dependent cellular cytotoxicity and phagocytosis, received accelerated approval in the USA and conditional authorization in Europe in combination with lenalidomide (LEN) for patients (pts) with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) ineligible for autologous stem cell transplant (ASCT) based on the results of the open-label, multicenter, single-arm, Phase II L-MIND study (NCT02399085; Salles G, et al. Lancet Oncol 2020, Duell J, et al. Haematologica 2021).

Aims:

Here, we report the final, 5-year follow-up of L-MIND. Data cut-off was Nov 14, 2022.

Methods:

Pts were aged ≥18 years with ASCT-ineligible R/R DLBCL, 1–3 prior systemic therapies (including a CD20-targeting regimen), and ECOG PS 0–2. Tafasitamab (12 mg/kg) was given for up to 12 cycles in combination with LEN (25 mg), then as monotherapy until disease progression (PD) or unacceptable toxicity. The primary endpoint was best objective response rate (ORR; complete response [CR] or partial response [PR], by independent radiology committee). Secondary endpoints included duration of response (DoR), progression-free survival (PFS), overall survival (OS), and incidence and severity of adverse events (AEs). Exploratory analyses evaluated efficacy endpoints by prior lines of therapy (pLoT).

Results:

Of 81 pts enrolled, 80 were treated (full analysis set [FAS]). The ORR (FAS) of 56.2% [95% CI: 44.7–67.3], with CR of 40.0% [29.2–51.6] (n=32) and PR of 16.2% [8.9–26.2] (n=13), was generally consistent with the primary and 3-year analyses. Median DoR was not reached (NR) with median follow up (mFU) of 43.7 months [29.9–58.4]. Median PFS was 11.6 months [5.7–45.7] (mFU 36.7 [22.9–59.2]) and median OS was 33.5 months [18.3–NR] (mFU

65.6 [59.9–70.3]). At data cut-off, OS was >60 months in 21 pts (18 with best response of CR, 1 PR, 1 stable disease and 1 PD), including 14 with 1 pLoT and 7 with ≥2 pLoT. Pts with 1 pLoT (n=40) in the FAS had higher ORR (65%; 50% CR [n=20] and 15% PR [n=6]) compared to pts with ≥2 pLoT (n=40; 47.5%; 30% CR [n=12] and 17.5% PR [n=7]). However, median DoR was not reached for both subgroups, indicating similar long-term efficacy for responders. AEs were consistent with previous reports and manageable; incidence declined after transition from combination to tafasitamab monotherapy and again with monotherapy >2 years.

Summary/Conclusion:

The final, 5-year analysis of L-MIND showed prolonged durable responses with tafasitamab + LEN combination therapy, followed by long-term tafasitamab monotherapy, in pts with R/R DLBCL ineligible for ASCT, with median DoR not reached after 43.7 months mFU. No new safety signals were identified, confirming the tolerability profile observed with earlier data cuts. These long-term data suggest that this immunotherapy may have curative potential that is being explored in further studies.

Duell, J et al. Five-year efficacy and safety of tafasitamab in patients with relapsed or refractory DLBCL: Final results from the Phase II L-MIND study [abstract]. In: Proceedings of the 114th Annual Meeting of the American Association for Cancer Research; 2023 April 9-14; Orlando, FL. Philadelphia (PA): AACR; 2023. Abstract nr CT022

Copyright Information: (Online) ISSN: 2572-9241

Abstract Book Citations: Authors, Title, HemaSphere, 2023;7(S3):pages. The individual abstract DOIs can be found at https://journals.lww.com/hemasphere/pages/default.aspx.