Abstract: P1214

Title: EARLYMIND, A RETROSPECTIVE MULTICENTER STUDY IN REAL-WORLD SETTINGS TO CHARACTERIZE TAFASITAMAB-LENALIDOMIDE EFFICACY IN TRANSPLANT-INELIGIBLE PATIENTS WITH RELAPSED/REFRACTORY LARGE B-CELL LYMPHOMA

Abstract Type: Poster Presentation

Topic: Aggressive Non-Hodgkin lymphoma - Clinical

Background:

Tafasitamab and lenalidomide combination therapy (TL) was approved in Europe in 2021 for the treatment of transplant-ineligible patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL). This approval was based on the L-MIND study, with the final 5-year analysis showing a 57.5% overall response rate, with a 41.3% complete response (CR) rate, a median progression-free survival (PFS) of 12.1 months, and median overall survival (OS) of 33.5 months (Duell et al. Haematologica. 2023).

Aims:

The multicenter retrospective EarlyMIND study analyzed the real-world efficacy of TL to describe treatment patterns of TL-treated patients who participated in the Expanded Access Program (EAP = "Accès Précoce") in France.

Methods:

Data on demographics, diagnosis, therapeutic lines, and efficacy outcomes were collected from patients who participated in the EAP from January 27, 2022 to March 31, 2023, and received TL in second (2L; cohort A) or third/fourth line (3/4L; cohort B). Endpoints included best overall response (BOR), duration of response, disease control rate, OS, PFS, and event-free survival. Subgroup analyses were performed based on refractory disease status, cell of origin, ECOG PS, IPI score, line of treatment, and response type. Safety data were collected through the EAP and were therefore not specifically collected for this study.

Results:

A total of 214 patients from 28 centers participating in the EAP were prescreened. 186 patients in total (cohort A, n=105; cohort B, n=81) with tumor response assessment available met the inclusion criteria and were included for analysis (per-protocol [PP] population). Patient characteristics at TL initiation are presented in the Table; overall median age was 78 years (cohort A: 81 years; cohort B: 74 years). Most patients (68.3%) had DLBCL not otherwise specified and primary refractory disease (60.9%). 33.3% of patients had ECOG PS ≥2 and 73.3% had IPI ≥3 at TL initiation. First line DLBCL treatments primarily included full-dose anthracycline-containing regimens (mainly R-CHOP; 52.7%), followed by R-mini-CHOP-like regimens (30.1%). Treatments received after TL were mostly R-chemo regimens. Thirteen patients received chimeric antigen receptor (CAR) T-cell therapy before and 5 received CAR T-cell therapy after TL.

At a median follow-up of 8.2 months, BOR of the PP population was 46.8% (95% CI, 39.4-54.2), with 29.0% (95% CI, 22.6-36.1) with CR and 17.7% (95% CI, 12.5-24.0) with partial response (PR). BOR of patients in cohort A and cohort B was 50.5% (95% CI, 40.6-60.4) and 42.0 % (95% CI, 31.1-53.5), respectively. In this population, 30.5% (95% CI, 21.9-40.2) were complete responders in cohort A and 27.2% (95% CI, 17.9-38.2) in cohort B. In the PP population, median PFS and OS were 4.7 months (95% CI, 3.6-6.0) and 10.0 months (95% CI, 8.4-13.4), respectively (Figure).

BOR in patients with ECOG PS ≤1 (58.2% [95% CI, 48.9-67.1]) were notably higher than that of patients with ECOG PS ≥2 (26.2% [95% CI, 15.8-39.1]; $P<0.001$, $\chi 2$ test). Patients with CR showed significantly longer PFS and OS (median not reached; $P<0.001$, log-rank test) compared with patients with PR (7.8 and 13.8 months,

respectively) and no response (2.2 and 4.0 months, respectively). Median time to achieve CR was 4.0 cycles in both cohorts A and B (Table).

Summary/Conclusion:

EarlyMIND is, to date, the largest retrospective real-world study of TL use in patients with R/R DLBCL in Europe. Despite the advanced age and high-risk disease characteristics of the study population, 29% of patients achieved CR, which appeared to be durable in this patient population with a high unmet need.

Keywords: NHL, CD19, B cell lymphoma, DLBCL