Clinical benefit of tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma: real-world data from the EarlyMIND study

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Received: December 10, 2024.
Accepted: May 6, 2025.
Early view: May 15, 2025.

https://doi.org/10.3324/haematol.2024.287141

Abstract

Tafasitamab combined with lenalidomide was approved in Europe in 2021 for transplant-ineligible patients with relapsed/refractory diffuse large B-cell lymphoma. Approval was based on the L-MIND study, which demonstrated a 57.5% overall

response rate (ORR), 41.3% complete response (CR) rate, 12.1-month median progression-free survival (PFS), and 33.5-month median overall survival (OS) at 5 years. The multicenter retrospective EarlyMIND study analyzed real-world efficacy and treatment patterns of patients receiving tafasitamab plus lenalidomide for second-line (2L cohort) to fourth-line (3L + 4L cohort) treatment in the French Early Access Program. Outcomes were analyzed overall and according to number of previous lines of treatment. *Post hoc* analyses were conducted on subgroups based on prognostic factors, performance status, primary refractoriness, cell of origin, and treatment response. Overall, 186 patients were included (2L: N=105; 3L + 4L: N=81). The median age of the patients was 78 years; most patients had early relapsed disease (71.2%), including 60.2% with primary refractory disease. At a median follow-up of 8.2 months, best ORR was 46.8%, with a CR rate of 29%. The ORR was higher in the 2L cohort (50.5%) than in the 3L + 4L cohort (42%). The median PFS and OS were 4.7 and 10 months, respectively, in the overall population, 5.4 and 10.6 months in the 2L cohort, and 3.6 and 8.2 months in the 3L + 4L cohort. Long-lasting responses were observed in patients achieving CR, with median duration of response, PFS, and OS not reached. The median time to CR as best objective response was four cycles, regardless of treatment line. Despite involving a frail population with high-risk disease characteristics, results of this large real-world European retrospective study on tafasitamab plus lenalidomide are encouraging, with almost one third of patients experiencing long-lasting CR.

Introduction

Diffuse large B-cell lymphoma (DLBCL) is the most common type of non-Hodgkin lymphoma, both globally and in Europe. The incidence rate in Europe is approximately 3.8 cases per 100,000 person-years,[1] with variation across different countries.[2] In France, 5,071 new cases of DLBCL were recorded in 2018, thus ranking this particular type of lymphoma as the most common histological subtype of non-Hodgkin lymphoma.[3] The combination of rituximab (R) and an anthracycline-based chemotherapy such as cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) constitutes the standard of care in France for first-line systemic treatment of newly diagnosed DLBCL.[1,4] Rituximab combined with attenuated chemotherapy, such as R-mini-CHOP, has been demonstrated to induce complete remission and is a gold standard as first-line treatment for older, fit patients (age >80 years).[5]

However, around 40% of patients experience relapsed or refractory (R/R) disease.[1,6] In the past 6 years, the salvage therapy landscape for R/R DLBCL has evolved rapidly since the arrival of autologous anti-CD19 chimeric antigen receptor (CAR) T-cell therapy. Axicabtagene ciloleucel and tisagenlecleucel became available for third-line treatment of R/R DLBCL in 2018 in France, and were quickly adopted as a standard of care for chemo-resistant patients, including those who were not eligible for autologous stem cell transplant (ASCT).[7-9] It is in this context that tafasitamab (a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody) in combination with lenalidomide was approved in Europe in August 2021, based on the results of the L-MIND study.[10,11] More recently, axicabtagene ciloleucel and lisocabtagene maraleucel have become indicated for patients with large B-cell lymphomas who do not respond or relapse in the 12 months following a first line with immunochemotherapy, demonstrating better efficacy than second-line salvage chemotherapy followed by ASCT,[12,13] and feasibility in transplant-ineligible patients.[14,15] Second-line CAR T-cell therapy for R/R DLBCL has been used in France through the country's Early Access Program (EAP) since July 2022 for ASCT-eligible and -ineligible patients who do not respond or relapse in the 12 months following treatment with R-CHOP.[16]

The single-arm phase II L-MIND study (NCT02399085) included 81 patients with R/R DLBCL who had received one to three prior lines of therapy and were not eligible for ASCT. Patients with primary refractory DLBCL, initially defined as those relapsing within 3 months of prior anti-CD20 therapy, were excluded from the trial. After a protocol amendment, primary refractory status was redefined as lack of response or progression during or within 6 months of frontline therapy. Consequently, patients who relapsed between 3 and 6 months before the amendment were included and assessed as primary refractory in the study. L-MIND demonstrated an objective response rate (ORR) of 57.5%, including a 41.3% complete response (CR) rate.[10,11] After 5 years of follow-up, the median duration of response (DOR) was not reached and median overall survival (OS) was 33.5 months, demonstrating durable responses and lasting benefits.[17] Common treatment-emergent adverse events included neutropenia (51%) and anemia (37%), decreasing after 12 cycles of combination therapy when transitioning to tafasitamab monotherapy after lenalidomide interruption. On January 27, 2022, tafasitamab plus lenalidomide was made available in France via an EAP.

Further investigation using real-world data is valuable to assess the treatment's effectiveness in practical clinical settings. One key aspect to explore is the impact of higher comorbidity rates among patients outside of a clinical trial. The EAP facilitated inclusion of a substantial cohort of patients, thereby allowing generation of real-world evidence through retrospective analysis. In this study, we present results of the EarlyMIND study, a multicenter, retrospective, non-interventional study that aimed to analyze real-world efficacy and describe treatment patterns of patients with R/R DLBCL treated with tafasitamab plus

lenalidomide in the French EAP.

Methods

EarlyMIND was conducted in compliance with the ethical rules of France, the Declaration of Helsinki, Good Clinical Practices and the *Méthodologie de Référence* MR-004 (compliance with MR-004 declared October 8, 2018); the study was registered with the Health Data Hub (N. F20230426191226) on April 26, 2023. All patients were informed about processing of their personal data, with those who did not object included.

Study design and patients

Study centers were selected from participating centers in the French EAP[18] based on their geographic distribution and number of patients; centers with three or more patients receiving tafasitamab plus lenalidomide in second line (regardless of how many received third or fourth line) were pre-selected (full details are provided in *Online Supplementary Table S1*).

Patients with R/R DLBCL, ineligible for ASCT, were treated with the tafasitamab plus lenalidomide combination as their second, third, or fourth line of treatment. Biopsy material was obtained from all patients and the histology was medically reviewed.

Tafasitamab was administered at a dose of 12 mg/kg intravenously, on days 1 and 15 of each 28-day cycle, until disease progression or death (whichever occurred first), according to the Summary of Product Characteristics (SmPC). Lenalidomide was self-administered at a dose of 25 mg orally, on days 1-21 of each 28-day cycle. The administration of lenalidomide was based on the SmPC. Lenalidomide was to be discontinued after a maximum of 12 cycles of the tafasitamab plus lenalidomide combination. After completing the combination therapy, tafasitamab was continued as monotherapy on days 1 and 15 of each 28-day cycle until disease progression or unacceptable toxicity.

Eligible patients had to be enrolled in the tafasitamab French EAP between January 27, 2022 and March 31, 2023. Patients treated in fifth or later line and/or patients who objected to retrospective collection of medical information were excluded.

The full analysis set included patients who received tafasitamab plus lenalidomide as second-, third-, or fourth-line therapy. The per protocol (PP) set included those patients in the full analysis set who fulfilled all inclusion/exclusion criteria with at least one efficacy assessment, progressive disease, or death within 6 months of follow-up. The population was divided into two cohorts: (i) patients who received tafasitamab as their second line of treatment (2L cohort), and (ii) patients who received tafasitamab as their third or fourth line of treatment (3L + 4L cohort).

Between September 16, 2023 and November 6, 2023, data were retrospectively collected from medical records using an electronic data capture tool (Ennov), and included patients' characteristics, disease-specific medical history, treatment patterns, tafasitamab plus lenalidomide dosage, and outcomes. Because overall safety results in the EAP population did not raise any new signals, safety data were not collected.[19]

Study outcomes

The primary endpoint was best objective response (bOR) (CR or partial response [PR]), assessed locally according to the 2007 International Working Group response criteria for malignant lymphoma.[20] Secondary endpoints included bOR per cohort, DOR, OS, PFS, event-free survival, disease control rate, time to next treatment, and treatment patterns. Details are provided in the *Online Supplementary Methods.*

Exploratory subgroup analyses

Exploratory subgroup analyses were performed according to primary refractory/non-primary refractory disease status; Eastern Cooperative Oncology Group performance status (ECOG PS; <2 *vs.* ≥2); International Prognostic Index (IPI) score (<3 *vs.* ≥3); DLBCL cell of origin (germinal center B-cell like [GCB]; GCB *vs.* non-GCB), and response type (CR *vs.* PR *vs.* no response). DOR, OS, and PFS were also assessed according to best-reported response (CR or PR).

Statistical analysis

The primary analysis was performed after data cut-off (November 6, 2023). Efficacy outcomes were analyzed in the PP set. Patients without disease assessment in the first 6 months, and who had stable disease, progressive disease or death thereafter were excluded from the analysis. Similarly, patients with stable disease during the first 6 months, and no further evaluation thereafter were also excluded.

Analyses were also performed on the full analysis set (data not presented; definition and details provided in the *Online Supplementary Methods*).

Primary and secondary endpoints were analyzed using the Kaplan-Meier method. Hazard ratios with 95% confidence intervals (95% CI) were estimated using Clopper-Pearson exact methods; *P* values were determined using a log-rank test. Statistical analyses were conducted using SAS® (version 9.3 or later).

Results

Patients' characteristics

Data were collected from 201 patients from 28 study centers up to the data cut-off date. Patients were enrolled in academic centers (60.2%), non-academic centers (29.9%), and private clinics (9.9%) (*Online Supplementary Table S1*). The PP set was established after a medical review by in-

vestigators and included 186 patients who received at least one dose of tafasitamab and who had been evaluated for response within a period of 6 months. No patients were excluded for reasons of toxicity leading to treatment discontinuation. One hundred five patients (56.5%) were enrolled in the 2L cohort and 81 (43.5%) were enrolled in the 3L + 4L cohort. A flowchart of the patients' disposition in the study is presented in Figure 1. The baseline characteristics of the PP set are presented in Table 1.

The median age at tafasitamab initiation was 78 years (range, 32-93 years); 80.1% of patients were aged ≥70 years, whereas <10% were aged <60 years. Of note, age was reported as the main reason for transplant ineligibility in the 2L cohort (72.4% of patients in this cohort) and the combination of age and age/comorbidities in the 3L + 4L cohort (85.2%). Two-thirds of patients (66.7%) had an ECOG PS of 0 or 1, and 73.1% had a high or intermediate-high IPI score. Most patients (68.3%) had DLBCL not otherwise specified (NOS); 14.5% had high-grade B-cell lymphoma, 10.8% had double- or triple-hit lymphoma, and 14.5% had transformed indolent lymphoma. The majority had primary refractory or early relapsed disease (71.2%), including 60.2% with primary refractory disease specifically.

Treatment exposure

The tafasitamab dose remained at 12 mg/kg for all patients, with a median number of cycles of 5 (interquartile range [IQR], 2-9) and a maximum number of cycles of 37. In the 2L cohort, the median duration of treatment was 5.2 months (IQR, 1.6-8.0). It was shorter in the 3L + 4L cohort, with a median of 3.4 months (IQR, 1.0-8.6).

The relative dose intensity of lenalidomide was 80%. The median duration of lenalidomide treatment was 3.4 months (IQR, 1.4-7.4 months). The median daily dose received (days 1-21 of each cycle) was 20.0 mg/day (IQR, 13.6-25.0 mg/day). Sixty-nine patients (37.1%) had a reduced dose of lenalidomide at initiation of treatment. Of these, two had an ECOG PS of 4, seven an ECOG PS of 3, 13 an ECOG PS of 2 and 44 had an ECOG PS of 0-1. Lenalidomide was discontinued before receiving 12 treatment cycles in ten patients (5.4%) with continuation of tafasitamab, and dose reduced in 59 patients (31.9%); the reasons were not collected as out of the study scope. Only one patient (0.5%) did not receive lenalidomide with tafasitamab at initiation and the reason

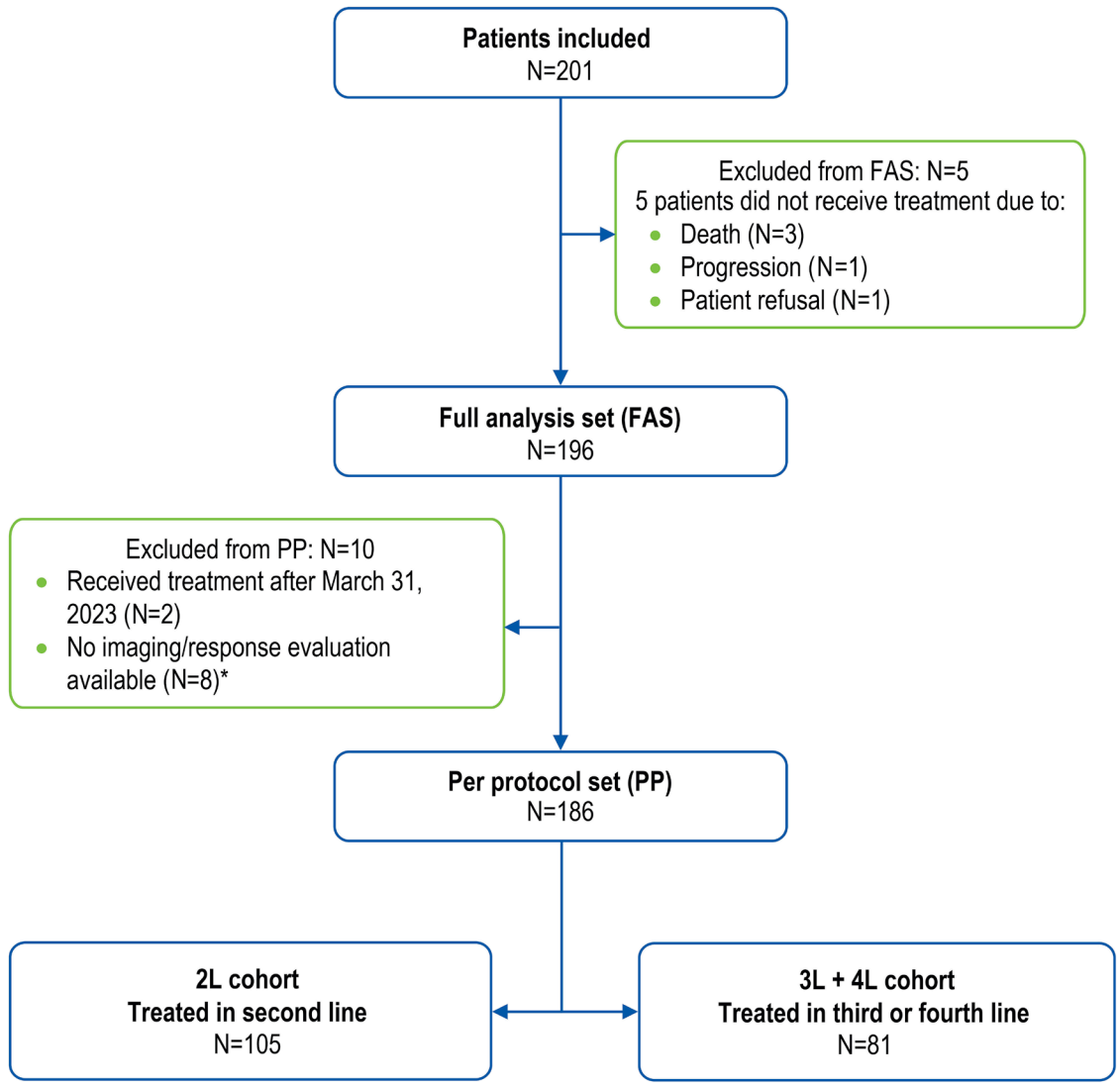

Figure 1. Flowchart of the patients' disposition in the EarlyMIND study. Disposition of enrolled patients. Eligible patients required enrollment in the tafasitamab French Expanded Access Program between January 27, 2022, and March 31, 2023. The full analysis set included patients who agreed to participate and received tafasitamab plus lenalidomide as second-, third-, or fourth-line therapy. The per-protocol set included those patients in the full analysis set who fulfilled all inclusion/exclusion criteria and had at least one evaluation of efficacy, with a minimum follow-up of 6 months. *Six without imaging, two with stable disease. 2L: second line; 3L: third line; 4L, fourth line; FAS: full analysis set; PP: per protocol.

Table 1. Patients' demographic and baseline clinical and disease characteristics (per-protocol set).

Characteristic	2L cohort N=105	3L + 4L cohort N=81	Total N=186
Female sex, N (%)	44 (41.9)	37 (45.7)	81 (43.5)
Age at tafasitamab initiation			
Median, years	81.0	74.0	78.0
Range, years	56-93	32-90	32-93
>70 years, N (%)	94 (89.5)	55 (67.9)	149 (80.1)
≤ 60 years, N (%)	5 (4.8)	13 (16)	18 (9.7)
Reason for transplant ineligibility, N (%)			
Age	76 (72.4)	40 (49.4)	116 (62.4)
Age/comorbidities	23 (21.9)	29 (35.8)	52 (28.0)
Age/non-chemosensitive	1 (1.0)	0 (0.0)	1 (0.5)
Other	3 (2.9)	6 (7.4)	9 (4.8)
Comorbidities	2 (1.9)	6 (7.4)	8 (4.3)
Eastern Cooperative Oncology Group Performance Status, N (%)			
<2	69 (66.3)	53 (67.1)	122 (66.7)
≥2	35 (33.7)	26 (32.9)	61 (33.3)
Missing	1	2	3
International Prognostic Index score, N (%)			
<3	32 (30.8)	17 (21.8)	49 (26.9)
≥3	72 (69.2)	61 (78.2)	133 (73.1)
Missing	1	3	4
Histology, N (%)			
DLBCL NOS	76 (72.4)	51 (63.0)	127 (68.3)
GCB-DLBCL	35 (52.2)	22 (47.8)	57 (50.4)
Non–GCB-DLBCL	32 (47.8)	24 (52.2)	56 (49.6)
Missing	9 (11.8)	5 (9.8)	14 (11.0)
Transformed indolent lymphoma	14 (13.3)	13 (16.0)	27 (14.5)
T-cell/histiocyte-rich large B-cell lymphoma	1 (1.0)	4 (4.9)	5 (2.7)
High-grade B-cell lymphoma	14 (13.3)	13 (16.0)	27 (14.5)
Double/triple hit, N (%)			
Yes	13 (22.4)	7 (13.7)	20 (18.3)
No	45 (77.6)	44 (86.3)	89 (81.7)
Missing	47 (44.8)	30 (37.0)	77 (41.4)
Refractory/relapsed, N (%)			
Primary refractory disease + early relapse	72 (69.2)	59 (73.7)	131 (71.2)
Primary refractory* (<6 months)	60 (83.3)	52 (88.1)	112 (85.5)
Early relapse (6-12 months)	12 (16.7)	7 (11.9)	19 (14.5)
Late relapse (≥12 months)	32 (30.8)	21 (26.3)	53 (28.8)
Refractory to last therapy	74 (71.2)	60 (75.0)	134 (72.8)
Missing	1	1	2
Prior chimeric antigen receptor T-cell therapy, N (%)	0 (0.0)	13 (16.0)	13 (7.0)
First-line systemic therapy prior to tafasitamab plus lenalidomide, N (%)			
R-CHOP-like regimen	42 (40.0)	56 (69.1)	98 (52.7)
R-mini-CHOP-like regimen	44 (41.9)	12 (14.8)	56 (30.1)
Low-intensity chemotherapy regimens[$]	11 (10.5)	6 (7.4)	17 (9.1)
High-intensity platinum-based regimens[#]	8 (7.6)	5 (6.2)	13 (7.0)
Other	0 (0.0)	2 (2.5)	2 (1.1)
Second-line systemic therapy prior to tafasitamab plus lenalidomide, N (%)			
R-CHOP-like regimen	–	2 (2.5)	2 (1.1)
R-mini-CHOP-like regimen	–	3 (3.7)	3 (1.6)
Low-intensity chemotherapy regimens[$]	–	39 (48.1)	39 (21.0)
High-intensity platinum-based regimens[#]	–	31 (38.3)	31 (16.7)
Other	–	6 (7.4)	6 (32.3)

*Defined as no response to, or progression during or within 6 months of front-line therapy, based on a healthcare professional's declaration. [$]The most frequent low-intensity regimens were rituximab, gemcitabine-oxaliplatin and rituximab, ifosfamide-etoposide. [#]Rituximab, dexamethasone, high-dose cytarabine, and carboplatin, cisplatin, or oxaliplatin (R-DHAC, P, or Ox). 2L: second line; 3L: third line; 4L: fourth line; DLBCL: diffuse large B-cell lymphoma; NOS: not otherwise specified; GCB: germinal center B cell; R-CHOP: rituximab, cyclophosphamide, doxorubicin, vincristine and prednisolone.

was not collected.

A total of 167 patients discontinued the combination of tafasitamab plus lenalidomide for the following reasons: progressive disease (N=116), death during treatment (N=16) and therapeutic decision (N=12). Of the 12 patients who discontinued treatment for therapeutic reasons, all were in CR or PR, but the clinical context encouraged discontinuation; reasons included suspicion of toxicity (N=4), the presence of concomitant diseases that required a different approach (N=5), patients' decision (N=2), and planned use of tafasitamab plus lenalidomide as a bridge for CAR T-cell therapy (N=1). The reason for discontinuation of the combination of tafasitamab plus lenalidomide was unknown in 23 patients, but some of them were reported by site investigators as patients in CR but elderly and with difficulty in commuting to the center.

Efficacy outcomes

With a median follow-up of 8.2 months (IQR, 3.6-13.4 months), the bOR was 46.8% (95% CI: 39.4-54.2). The bOR was 50.5% (95% CI: 40.55-60.38) for patients in the 2L cohort and 42.0% (95% CI: 31.09-53.46) for patients in the 3L + 4L cohort. Overall, 54 of 186 patients (29.0%) had a CR (32/105 in the 2L cohort [30.5%], 22/81 in the 3L + 4L cohort [27.2%]), whereas 33 (17.7%) had a PR as bOR (21 in the 2L cohort, 12 in the 3L + 4L cohort) (Figure 2).

The median OS in the PP population was 10.0 months (95% CI: 8.4-13.4) and the median PFS was 4.7 months (95% CI: 3.6-6.0) (Figure 3A, B). The median OS and PFS were 10.6 (95% CI: 9.4-17.0) and 5.4 (95% CI: 4.0-7.8) months, respectively, in the 2L cohort, and 8.2 (95% CI: 4.8-13.8) and 3.6 (95% CI: 2.6-6.0) months, respectively, in the 3L + 4L cohort. The median DOR was 13.4 months in patients achieving at least a PR (95% CI: 8.8 to not evaluable) (Figure 4, Table 2) and was not reached in patients achieving a CR (Figure 4). The median time to next treatment was 3.8 months, with values ranging from 0.6 to 14.2 months overall. Of note, 81 patients were still alive at data cut-off, among whom 44 (54.3%) were still being treated with tafasitamab plus lenalidomide.

Treatment patterns

Of 186 patients, 105 (56.5%) received one line of therapy prior to tafasitamab plus lenalidomide, 54 (29.0%) received two lines, and 27 (14.5%) received three lines (*data not shown*). The most frequent regimen administered in the overall population as first line prior to tafasitamab plus lenalidomide was an anthracycline-containing regimen (R-CHOP or R-CHOP–like) (52.7%), followed by R-mini-CHOP or R-mini-CHOP-like regimens (30.1%). Most patients treated with tafasitamab plus lenalidomide in the 3L + 4L cohort had received low-intensity chemotherapy regimens (R with chemotherapy) (48.1%) in second line (mainly R-gemcitabine, oxaliplatin), and 38.3% had received high-intensity chemotherapy regimens (R-cytarabine ± platinum) (Table 1).

Only 13 patients (7.0%) received CAR T-cell therapy before tafasitamab plus lenalidomide, with most of the patients receiving CAR T-cell as third-line therapy (*data not shown*). The median time from CAR T-cell infusion to combination therapy was 4.4 months (IQR, 3.98-6.28 months). Treatment outcomes are provided in *Online Supplementary Table S2*. Of note, determination of CD19 expression by immunohistochemistry was rarely done (8.6% at initiation of tafasitamab plus lenalidomide treatment), but was positive in 15 out of 16 cases.

Five patients received CAR T-cell therapy after tafasitamab, mainly in the 2L cohort, immediately after the tafasitamab plus lenalidomide combination (*data not shown*).

Thirty-six percent of patients received a new treatment line after tafasitamab plus lenalidomide, mainly in the 2L cohort (58.7%). Two-thirds (67.2%) received one line, 28.4% received two lines, and three (4.5%) received up to three lines of therapy after tafasitamab plus lenalidomide.

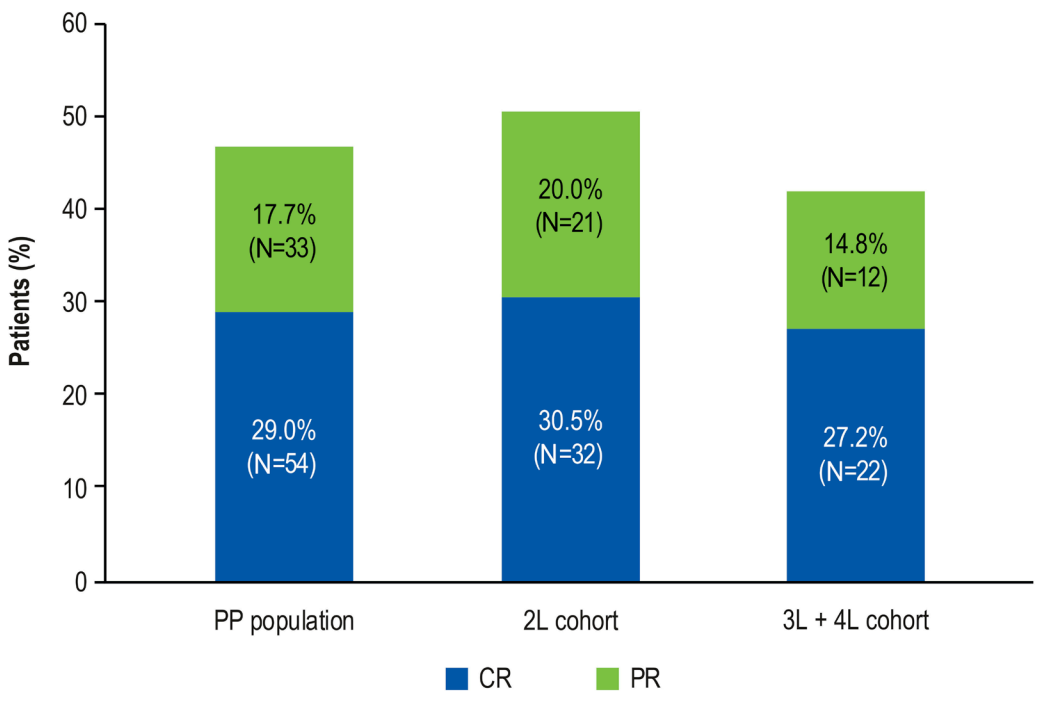

Figure 2. Best objective response for the per protocol population (N=186) and the subsets of patients treated in second line (N=105) and third + fourth line (N=81). PP: per protocol; 2L: patients treated in second line; 3L + 4L: patients treated in the third + fourth line; CR: complete response; PR: partial response.

Treatment details are provided in *Online Supplementary Table S3A, B*.

Exploratory subgroup analyses

Subgroup analyses displaying statistical differences are

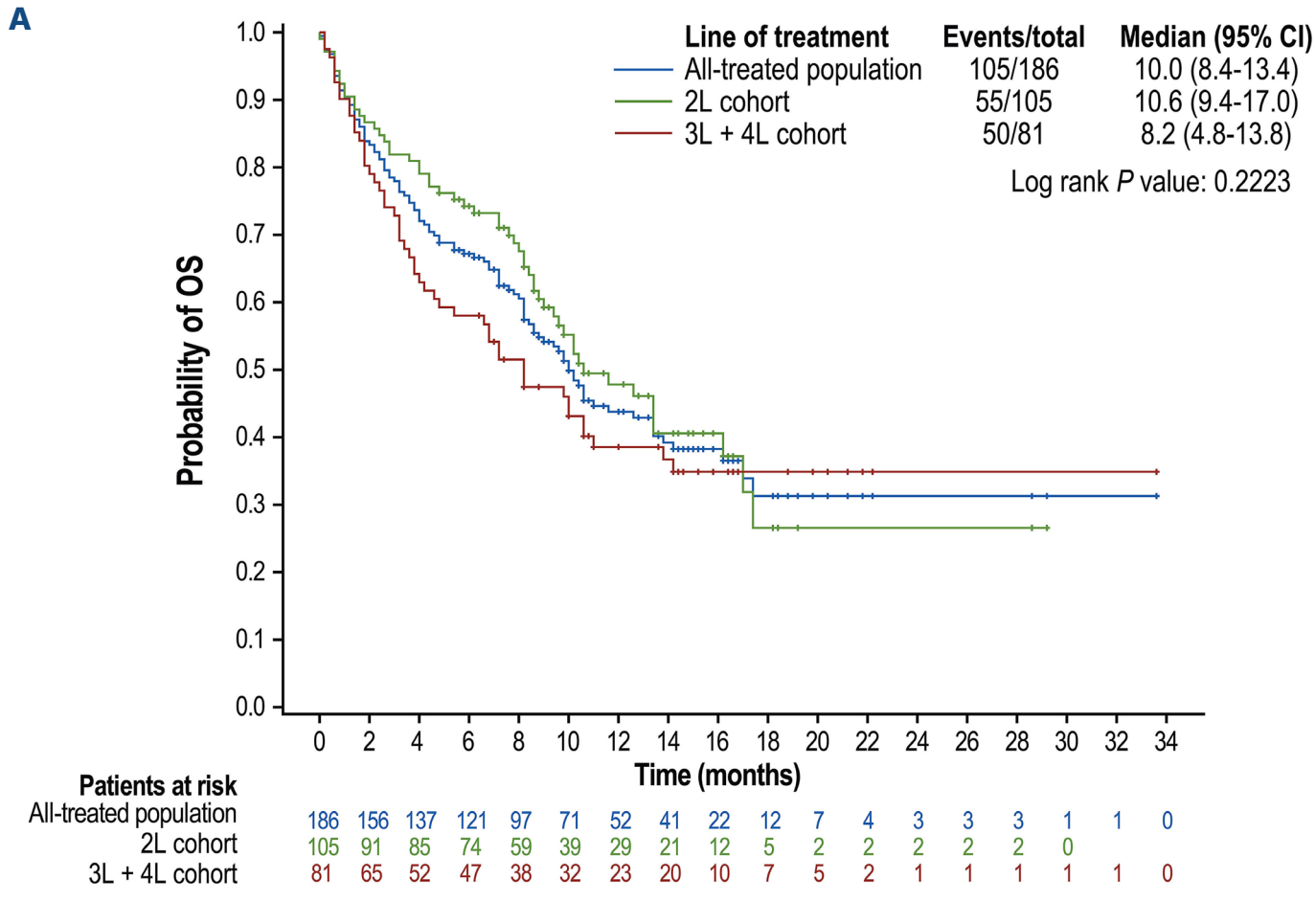

Figure 3. Overall survival and progression-free survival in the overall population, and in the subsets of patients treated in second line and third + fourth line. (A, B) Kaplan-Meier curves illustrating overall survival (A) and progression-free survival (B) for the per protocol population (N=186) and 2L and 3L+4L cohorts. Tick marks indicate censored patients. Log-rank *P* values are for the comparison of the 2L cohort *versus* the 3L+4L cohort. OS: overall survival; 95% CI: 95% confidence interval; 2L: patients treated in second line; 3L+4L: patients treated in third + fourth line; PFS: progression-free survival.

shown in Table 2. Patients with ECOG PS <2 had significantly higher bOR, OS, and PFS in the overall population and in both cohorts (Table 2 and *Online Supplementary Figure S1*). Similarly, non-primary refractory patients had higher bOR, OS, and PFS in the overall population (Table 2). No statistically significant differences in efficacy endpoints were observed based on cell of origin (*data not shown*).

Overall, 53 of 131 (40.5%) patients who progressed early achieved a bOR compared to 34 of 53 (64.2%) who had late relapses. Among the early-progressing patients, 27.5% achieved CR compared to 34% of the late-relapse patients. A statistically significant difference in bOR was observed between early-progressing and late-relapse patients (P=0.0036, *data not shown*).

Patients with CR had significantly longer OS and PFS than patients with PR (P<0.0001) (Figure 5), with the median OS and median PFS not reached in the CR group compared with 13.8 and 7.8 months, respectively, for the PR group. Similarly, patients with CR had a significantly longer DOR compared with that of patients with PR (P<0.0001), with the median DOR not reached in the CR group compared with 4.2 months for patients in the PR group (Figure 4). Also, time to best response was short, within a median of 4.0 cycles (15.3 weeks) (*Online Supplementary Table S4*).

Based on these observations, we analyzed baseline characteristics of patients with CR in the PP population (N=54). The median age was 79 years, 83.3% had ECOG PS 0-1, and 55.6% had DLBCL NOS, but histologies were mixed in the remaining patients (7.4% T-cell/histiocyte-rich large B-cell lymphoma, 18.5% transformed indolent lymphoma; 18.5% high-grade B-cell lymphoma). Most patients had high-risk features, such as an IPI score of 3-5 (63.0%) and primary refractory disease (55.6%). These data are presented in *Online Supplementary Table S2*. The prevalence of early-line patients was higher than that of late-line patients (59.3% second line; 40.7% third and fourth line) (*data not shown*).

Discussion

This study represents the largest retrospective real-world evaluation of patients with R/R DLBCL treated with tafasitamab plus lenalidomide in Europe. Overall, a significant proportion of patients displayed high-risk features (advanced age, primary refractory disease, IPI 3-5). After a median follow-up of 8.2 months, bOR was 46.8%, with 29.0% of patients achieving CR. The bOR was numerically higher in patients treated in the 2L cohort (50.5%) than those treated in the 3L

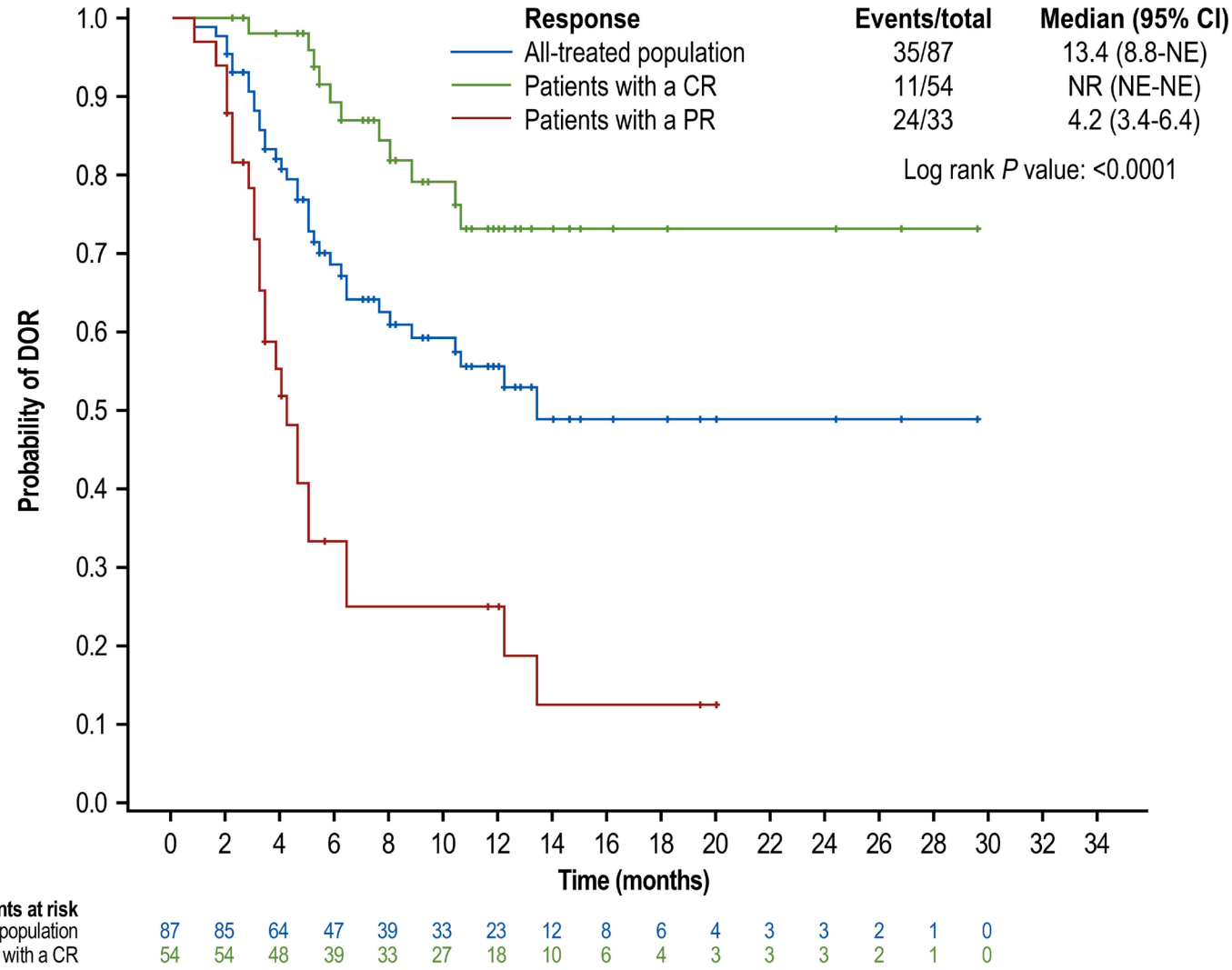

Figure 4. Duration of response in the per protocol population and subpopulations with complete or partial responses. Kaplan-Meier curves illustrating the duration of response for the per protocol population (N=186) and the subsets of patients with a complete response (N=54) or a partial response (N=33). Tick marks indicate censored patients. Log-rank *P* values are for the comparison of patients with complete response *versus* those with a partial response. DOR: duration of response; 95% CI: confidence interval; CR: complete response; PR: partial response; NE: not evaluable; NR: not reached.

Table 2. Efficacy endpoints showing statistical differences between subgroups based on primary refractoriness, prognosis and performance status, line of treatment, and treatment response.

Endpoint	Characteristic	Subgroup	N	% (95% CI)	*P*
bOR	Refractory disease	PP set Non–primary refractory Primary refractory	184 72 112	 59.7 (47.50-71.12) 39.3 (30.19-48.96)	0.0067
bOR	Refractory disease	2L cohort Non–primary refractory Primary refractory	104 44 60	 65.9 (50.08-79.51) 40.0 (27.56-53.46)	0.009
bOR	ECOG PS	PP set ECOG PS <2 ECOG PS ≥2	184 122 61	 58.2 (48.93-67.06) 26.2 (15.80-9.07)	<0.001
bOR	ECOG PS	2L cohort ECOG PS <2 ECOG PS ≥2	104 69 35	 62.3 (49.83-73.71) 28.6 (14.64-46.30)	0.0011
bOR	ECOG PS	3L + 4L cohort ECOG PS <2 ECOG PS ≥2	79 53 26	 52.8 (38.64-66.70) 23.1 (8.97-43.65)	0.0121
bOR	IPI	3L + 4L cohort IPI <3 IPI ≥3	104 32 72	 70.6 (44.04-89.69) 36.1 (24.16-49.37)	0.0111
Endpoint	**Characteristic**	**Subgroup**	**N**	**Months (95% CI)**	***P***
DOR	Response	PP set CR PR	87 54 33	13.4 (8.8-NE) NE (NR) 4.2 (3.4-6.4)	<0.0001
OS	Refractory disease	PP set Non–primary refractory Primary refractory	184 72 112	 11.6 (9.8-NE) 8.2 (7.2-12.6)	0.0415
OS	ECOG PS	PP set ECOG PS <2 ECOG PS ≥2	183 122 61	 13.8 (10.4-NE) 4.0 (2.2-9.8)	<0.001
OS	ECOG PS	2L cohort ECOG PS <2 ECOG PS ≥2	104 69 35	 13.4 (10.6-NE) 4.4 (2.6-12.6)	0.0001
OS	ECOG PS	3L + 4L cohort ECOG PS <2 ECOG PS ≥2	79 53 26	 10.6 (7.2-NE) 2.7 (1.8-11.0)	0.0043
OS	IPI	PP set IPI <3 IPI ≥3	182 49 133	 13.4 (10.4-NE) 9.0 (7.8-12.6)	0.0301
OS	IPI	3L + 4L cohort IPI <3 IPI ≥3	104 32 72	 NE (NR) 7.2 (3.8-10.6)	0.0399
OS	Response	PP set CR PR	186 54 33	 NE (NR) 13.8 (10.2-NE)	<0.0001
PFS	Refractory disease	PP set Non–primary refractory Primary refractory	184 72 112	 6.6 (5.6-10.6) 3.6 (2.8-5.2)	0.0386
PFS	ECOG PS	PP set ECOG PS <2 ECOG PS ≥2	183 122 61	 6.0 (5.0-8.8) 2.2 (1.6-3.6)	<0.0001
PFS	ECOG PS	2L cohort ECOG PS <2 ECOG PS ≥2	104 69 35	 6.8 (5.8-11.6) 2.6 (1.6-5.2)	0.0037
PFS	ECOG PS	3L + 4L cohort ECOG PS <2 ECOG PS ≥2	79 53 26	 5.6 (3.2-9.8) 2.1 (1.4-5.6)	0.0028

Continued on following page.

Endpoint	Characteristic	Subgroup	N	Months (95% CI)	*P*
PFS	IPI	3L + 4L cohort IPI <3 IPI ≥3	104 32 72	 9.8 (3.8-NE) 3.6 (2.2-5.6)	0.0211
PFS	Response	PP set CR PR	186 54 33	 NE (NR) 7.8 (6.0-10.6)	<0.0001

95% CI: 95% confidence interval; bOR: best objective response; PP: per protocol; 2L: second line; ECOG PS: Eastern Cooperative Oncology Group performance status; 3L: third line; 4L: fourth line; IPI: International Prognostic Index; DOR: duration of response; NE: not evaluable; NR: not reached; OS: overall survival; CR: complete response; PR: partial response; PFS: progression-free survival.

+ 4L cohort (42.0%). The median PFS and OS in the overall population were 4.7 months and 10.0 months, respectively. Importantly, despite the relatively short follow-up, the median PFS, OS, and DOR were not reached for patients achieving CR, suggesting that durable remissions may be achieved for a subset of patients, as previously observed in the L-MIND trial.[10,11,17] Among patients achieving CR, we were unable to identify a typical clinical profile more likely to respond to treatment, as CR was observed in a diverse set of patients, including those with high-risk features, such as elevated IPI score, primary refractory disease, or high-grade B-cell lymphoma histology. Interestingly, four of five patients with T-cell/histiocyte-rich large B-cell lymphoma, an entity known for its poor response to anti-CD19 CAR T-cell therapy,[21] achieved a CR.

Additionally, our study explored efficacy endpoints in diverse subgroups, with ECOG PS, followed by primary refractory status, as the parameters with the highest impact on treatment outcomes.

The results of our real-life study provide valuable insights into the outcomes of treatment with tafasitamab plus lenalidomide and the characteristics of patients who may benefit from this immunotherapy combination outside of clinical trials in the current treatment landscape. In the pivotal L-MIND study, patients were younger (median age 72 years), and there was a much lower proportion of primary refractory patients (18.8% had relapsed between 3 and 6 months after first-line treatment).[10,11] Additionally, almost all patients had ECOG PS 0-1 (91.4%), and only 51.0% had an IPI 3-5. These differences in patients' profiles likely explain the better outcomes in L-MIND than those in the current study. These data show that a subset of patients with DLBCL are sensitive to tafasitamab plus lenalidomide and achieve good quality remission; however, we lack a reliable tool to identify these patients confidently.

Other studies of real-world outcomes with tafasitamab plus lenalidomide have been reported. A retrospective study by Qualls *et al*. evaluated outcomes in 178 patients with R/R DLBCL treated with tafasitamab plus lenalidomide at 11 institutions in the USA.[22] After 6.5 months of follow-up, reported outcomes were numerically inferior to those of our cohort (bOR 31% *vs*. 46.8%, CR 19% *vs*. 29%, median PFS 1.9 months *vs*. 4.7 months, median OS 6.5 months *vs*. 10 months). The characteristics of the patients were different from those in our study, with a higher number of prior lines of treatment, 38% of patients treated in fourth line or beyond, and more patients with poor ECOG PS, including 13% with ECOG PS ≥3. Primary refractory patients represented 49% of the USA cohort, which is a higher proportion than in L-MIND, but lower than in our study. Other patients' characteristics were similar to those of the population of our study (median age 75 years, 54% had DLBCL NOS, 73% had IPI 3-5). Taken together, in this more heavily pre-treated population, with a greater number of patients with poor ECOG PS, it is not surprising to observe that tafasitamab plus lenalidomide outcomes were poorer.

Similar results were reported in another recent retrospective analysis presented at the American Society of Hematology 2023 Annual Meeting by Ruckdeschel *et al*. who evaluated outcomes of 127 patients treated with tafasitamab plus lenalidomide in Germany and Austria.[23] After 10.1 months of follow-up, the bOR was 33%, CR 12%, median PFS 4.7 months, and median OS 8.9 months. Differences in patients' characteristics *versus* the EarlyMIND cohort included a higher number of prior lines of treatment, with 55.1% of patients treated in fourth line or beyond, lower proportions of primary refractory patients (43%) and patients with IPI 3-5 (55%), and a higher proportion of DLBCL NOS histology (87%). The median age of patients was comparable to that in our study (73 years), and ECOG PS was not reported.

A recent analysis by Camus *et al*. evaluated 67 patients from the DESCAR-T registry treated with axicabtagene ciloleucel or tisagenlecleucel in at least third line.[24] In the 52 patients treated with tafasitamab plus lenalidomide, mainly in fourth line and after CAR T-cell therapy, the bOR and best CR rates were 13.5% and 7.7%, respectively, with a median PFS since first treatment for progression of 3 months and median OS since first treatment for progression of 4.7 months. Notably, patients relapsing >6 months after CAR T-cell therapy had better outcomes than those relapsing earlier, with a median PFS since first treatment for progression of 5.6 months and median OS since first treatment for progression not reached, suggesting that tafasitamab plus lenalidomide may offer improved outcomes for patients relapsing >6 months after CAR T-cell therapy.

Finally, real-life outcomes from a cohort in the USA includ-

ing 181 patients, of whom 168 had evaluable outcomes after tafasitamab plus lenalidomide, reported at the American Society of Hematology 2023 Annual Meeting by Saverno *et al.* showed a bOR of 75.6% and CR 18.5%, with the median

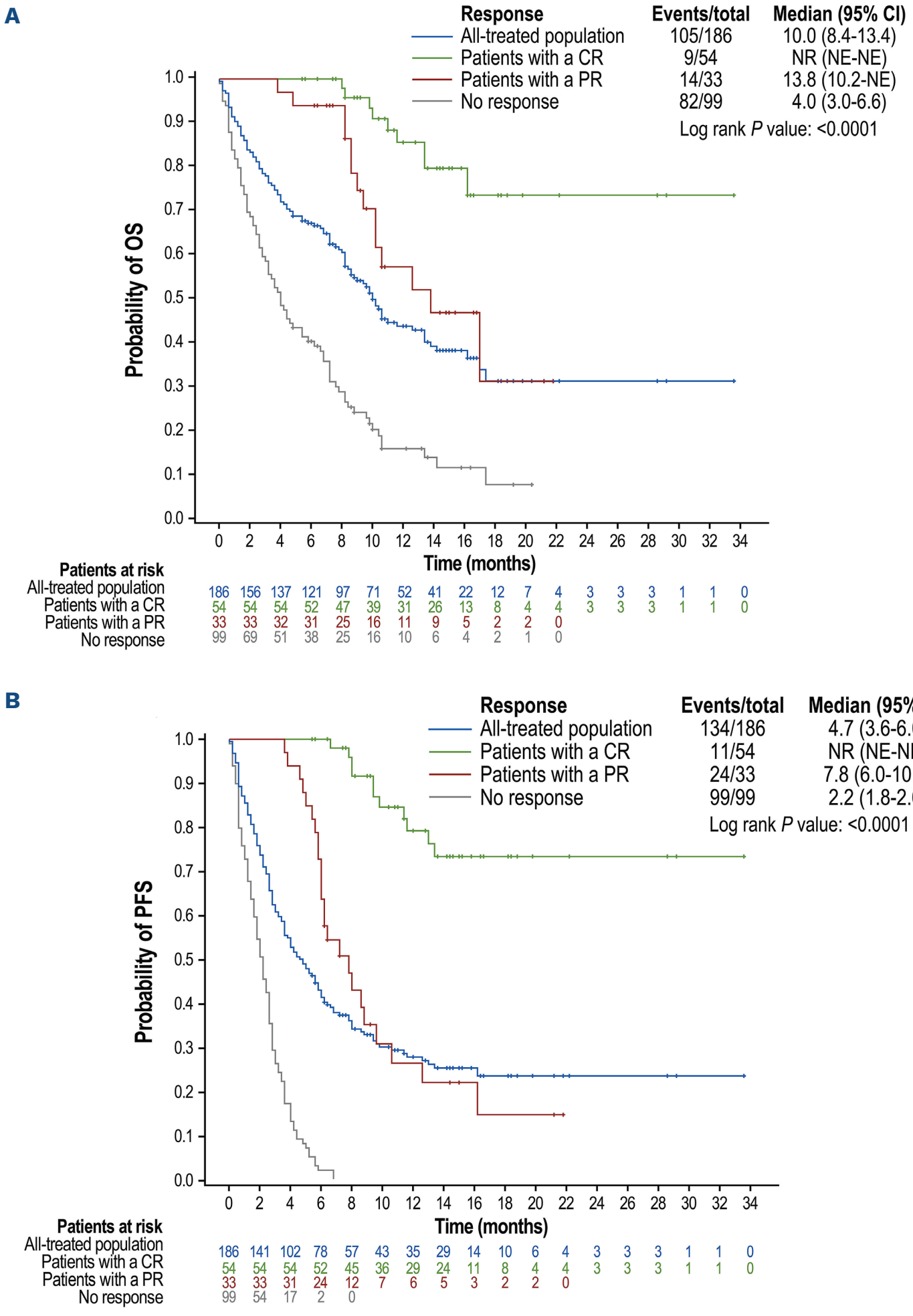

Figure 5. Overall survival and progression-free survival in the subpopulations with complete or partial responses. (A, B) Kaplan-Meier curves illustrating overall survival (A) and progression-free survival (B) for the per protocol population (N=186) and the subsets of patients with a complete response (N=54) or a partial response (N=33). Tick marks indicate censored patients. Log-rank *P* values are for the comparison of patients with complete response *versus* those with a partial response. OS: overall survival; CR: complete response; PR: partial response; 95% CI: confidence interval; NR: not reached; NE: not evaluable; PFS: progression-free survival.

PFS and OS not reached after a median follow-up of 6.5 months.[25] The population in this study was less heavily pre-treated than those in the other real-world studies, with 72% of patients treated in second line, 24% in third line, and only 5% in fourth line or beyond; the proportion of primary refractory patients was also markedly lower (26%). Almost all patients had ECOG PS 0-2 (98.3%), and most had IPI 3-5 (80.5%). The median age of the patients was comparable to that in all other studies (71.1 years).

The disparity in terms of efficacy observed between L-MIND and real-world data reports may thus be associated with the characteristics of the respective populations studied. Importantly, only 14.3% of EarlyMIND patients, 22% of patients in the study by Qualls *et al.*,[22] and 37% of patients in the study by Ruckdeschel *et al.*[23] would have been eligible for L-MIND (see *Online Supplementary Table S5* for reasons for ineligibility of EarlyMIND patients). In general, most real-life patients exposed to tafasitamab plus lenalidomide appear to be >70 years of age, with additional predictors of unfavorable survival, such as IPI 3-5. As may be expected, outcomes appear worse in populations with a higher proportion of heavily pre-treated patients and/or primary refractory patients. In EarlyMIND, the proportion of patients who were primary refractory was the highest of all the available studies, however, response to the treatment did not vary significantly between early-progressing patients and late-relapse patients. In contrast, the line of treatment in which tafasitamab plus lenalidomide was administered was restricted to the second, third, and fourth lines. The results of this study show clinical benefits, especially for patients achieving a CR, irrespective of primary refractory status.

EarlyMIND has several limitations including, but not limited to, the retrospective design of the study, representation of academic centers and non-academic centers *versus* the overall proportion of each type of center in the French EAP (53.1% of non-academic centers in the EAP *vs*. 39.2% in EarlyMIND, 25.7% academic centers in the EAP *vs*. 50.0% in EarlyMIND), lack of consistency in response evaluations/imaging in real-life conditions, and most importantly, the relatively short duration of follow-up (8.2 months, which is consistent with other real-life studies). To note, histology of the relapses before tafasitamab plus lenalidomide initiation (transformed indolent lymphoma according to routine practice) was not collected. It should be noted that all patients in EarlyMIND had to have received at least one dose of tafasitamab, and in this analysis, 16.7% of patients did not complete a full treatment cycle.

This study represents the largest retrospective real-world evaluation of treatment with tafasitamab for R/R DLBCL in Europe. Despite involving a frail population with high-risk disease characteristics, our results show significant clinical benefits for a subset of patients, including 29.0% of patients with CR, which were long-lasting. Considering the findings of our study, tafasitamab plus lenalidomide seems to be a good option for patients with R/R DLBCL, who are ineligible for CAR-T cell therapy in 2L. Notably, bispecific antibodies are not currently available in France for use in 2L. This regimen should also be considered for patients relapsing following CAR-T cell therapy and bispecific antibodies and for whom chemotherapy is not an option. These results are particularly encouraging, given the high unmet therapeutic need of R/R DLBCL patients with advanced age and/or frail status.

Disclosures

LJ reports employment by and stock ownership in Incyte Corporation. SB reports honoraria from Incyte. GB reports board participation, expenses for travel/congress participation, advisory board and training from Incyte. CHa reports consulting fees or honoraria from AbbVie, BMS, Kite/Gilead, Roche, Incyte, Takeda and Miltenyi and membership of a board or advisory committee for AbbVie, BMS, Incyte, Kite Gilead, Miltenyi, MSD, Roche and SOBI. CHe reports consulting fees or honoraria from AbbVie, Kite/Gilead, Roche and Incyte; travel/accommodation expenses from AbbVie, Incyte, Kite Gilead and Roche; and research funding from AbbVie and Takeda. FM reports board participation for AbbVie, Amgen and Incyte. JP reports honoraria from Incyte. OT reports travel grants and/or honoraria from AbbVie, AstraZeneca, BeiGene, Blueprint, Galapagos, Incyte, Novartis and Takeda. The other authors had no conflicts of interest to disclose.

Contributions

GB, JP, SB, OT, L-MF, FM, LG, ED, AT, TB, VI, BC, CS, JD, AEY, BD, LL, EL, CV, PA, GE, LF, CN, GO, AL, A-SLB, OC, CHa and CHe collected data. CHe, CHa, SB, GB, OT and JP interpreted the data. GB, JP, SB, OT, L-MF, FM, LG, ED, AT, TB, VI, BC, CS, JD, AEY, BD, LL, EL, CV, PA, GE, LF, CN, GO, AL, A-SLB, OC, LJ, CHa and CHe drafted and reviewed the manuscript.

Acknowledgments

The authors thank the patients, caregivers, and study investigators. Euraxi Pharma (CRO) contributed to data collection, curation, and analysis. Medical writing assistance was provided by CMediClimb in accordance with Good Publication Practice and editorial and graphics support was provided by Envision Pharma Group (Fairfield, CT, USA).

Funding

This study was sponsored by Incyte Biosciences International Sàrl Editorial and graphics support was funded by Incyte Corporation (Wilmington, DE, USA).

Data-sharing statement

Incyte Corporation (Wilmington, DE, USA) is committed to data sharing that advances science and medicine while protecting patients' privacy. Qualified external scientific researchers may request anonymized datasets owned by Incyte for the purpose of conducting legitimate scientific research. Researchers may request anonymized datasets from any interventional study (except phase I studies) for which the product and indication

have been approved on or after January 1, 2020, in at least one major market (e.g., US, EU, JPN). Data will be available for request after the primary publication or 2 years after the study has ended. Information on Incyte's clinical trial data-sharing policy and instructions for submitting clinical trial data requests are available at: https://www.incyte.com/Portals/0/Assets/Compliance%20and%20Transparency/clinical-trial-data-sharing.pdf?ver=2020-05-21-132838-960.

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