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Primary Outcomes From the Phase 3 Study of Tafasitamab Plus Lenalidomide and R-CHOP for Patients With Newly Diagnosed Diffuse Large B-Cell Lymphoma (frontMIND)

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Introduction

- Diffuse large B-cell lymphoma (DLBCL) is the most common lymphoma, accounting for 25-45% of non-Hodgkin lymphoma cases worldwide[1]
- R-CHOP (rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone or prednisolone) is a standard, first-line, curative-intent treatment for DLBCL[2,3]
- However, >40% of patients with high-risk DLBCL are not cured with first-line R-CHOP[4-6]
- Tafasitamab, a CD19-targeted monoclonal antibody, in combination with lenalidomide doubled the historical objective response rate (ORR) of lenalidomide monotherapy in relapsed/refractory DLBCL, leading to FDA approval of the regimen in this setting[7,8]
- Tafasitamab plus lenalidomide added to R-CHOP (Tafa-Len-R-CHOP) demonstrated encouraging safety and efficacy in the phase 1b First-MIND study of patients with previously untreated DLBCL[9]
- Here, we present primary results and additional exploratory analyses from the frontMIND study of Tafa-Len-R-CHOP as first-line treatment in DLBCL
  - Detailed results from the primary analysis have been published[10]

Objective

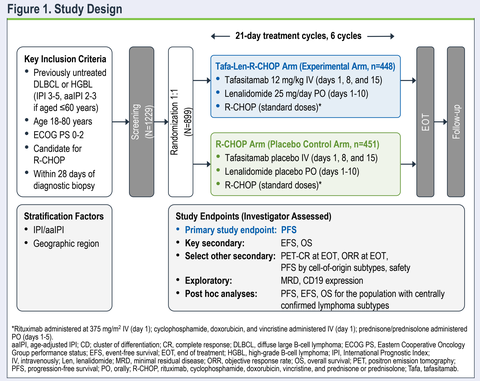
- The frontMIND study (NCT04824092) aimed to evaluate Tafa-Len-R-CHOP vs R-CHOP in untreated patients with high intermediate- or high-risk DLBCL or high-grade B-cell lymphoma (HGBL)

Methods

frontMIND Study Design and Treatment

- frontMIND was a phase 3, global, multicenter, randomized, placebo-controlled, double-blind study conducted at 298 centers in North America, South America, Europe, and the Asia-Pacific region
- The study design, including key inclusion criteria, stratification factors, and study endpoints, is shown in **Figure 1**

Figure 1. Study Design



*Rituximab administered at 375 mg/m² IV (day 1); cyclophosphamide, doxorubicin, and vincristine administered IV (day 1); prednisone/prednisolone administered PO (days 1-5).
aaIPI, age-adjusted IPI; CD, cluster of differentiation; CR, complete response; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; EOT, end of treatment; HGBL, high-grade B-cell lymphoma; IPI, International Prognostic Index; IV, intravenously; Len, lenalidomide; MRD, minimal residual disease; ORR, objective response rate; OS, overall survival; PET, positron emission tomography; PFS, progression-free survival; PO, orally; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone or prednisolone; Tafa, tafasitamab.

Assessments

- Imaging assessments were performed during screening, at the end of cycle 3, after the end-of-treatment (EOT) visit, and every 6 months during the follow-up period
- Fluorodeoxyglucose-positron emission tomography (FDG-PET) scans were mandatory at screening and at EOT
- All patients were required to have archival or freshly collected tumor tissue submitted for central pathology and gene expression profiling (GEP); eligibility of patients was based solely on local pathological assessment
- Central laboratory GEP of tumor specimens was used to assess cell-of-origin (COO) subtypes in all samples with sufficient available tissue, using the NanoString platform (NanoString Technologies, Seattle, WA, USA)
- Minimal residual disease (MRD) status was assessed based on capture-based ctDNA assay at baseline and EOT
- CD19 expression in tumor biopsies was assessed by immunohistochemistry and reviewed and reported by central pathologists; biopsies at the time of progression were not mandatory
- The study was powered to assess progression-free survival (PFS), triggered when 274 PFS events occurred that would provide approximately 83% power, at a 2-sided 5% significance level, to claim superiority of the experimental vs control treatment

Results

Patient Characteristics

- At the primary analysis data cutoff (October 20, 2025), 899 patients had been randomized to receive Tafa-Len-R-CHOP (n=448) or R-CHOP (n=451) **(Figure 1)**
- Baseline demographics and disease characteristics were balanced between treatment groups **(Table 1)**

Table 1. Demographics and Baseline Disease Characteristics (ITT Population)

Characteristic	Tafa-Len-R-CHOP (n=448)	R-CHOP (n=451)	Total (N=899)
Median age, years (range)	65.0 (20, 80)	65.0 (18, 80)	65.0 (18, 80)
Male sex, n (%)	240 (53.6)	233 (51.7)	473 (52.6)
Ann Arbor stage III or IV at enrollment, n (%)	432 (96.4)	436 (96.7)	868 (96.6)
Extranodal involvement at ≥2 sites, n (%)	173 (38.6)	175 (38.8)	348 (38.7)
Elevated lactate dehydrogenase level, n (%)	369 (82.4)	376 (83.4)	745 (82.9)
Presence of bulky disease, n (%)	254 (56.7)	231 (51.2)	485 (53.9)
ECOG PS at screening, n (%)			
0-1	311 (69.4)	305 (67.6)	616 (68.5)
2	137 (30.6)	146 (32.4)	283 (31.5)
Risk group (stratification factor) , n (%)			
High-intermediate risk (IPI 3/aaIPI 2)	259 (57.8)	244 (54.1)	503 (56.0)
High risk (IPI 4-5/aaIPI 3)	186 (41.5)	202 (44.8)	388 (43.2)
Median time from diagnostic biopsy to treatment initiation, days (Q1, Q3)	23.5 (17, 28)	24.0 (18, 28)	24.0 (18, 28)
Lymphoma subtype (local assessment), n (%)			
DLBCL	362 (80.8)	361 (80.0)	723 (80.4)
HGBL with *MYC* and *BCL2* and/or *BCL6* rearrangements	34 (7.6)	37 (8.2)	71 (7.9)
Other*	52 (11.6)	53 (11.8)	105 (11.7)
Lymphoma subtype (retrospective central assessment), n/N (%)			
DLBCL	307/391 (78.5)	325/382 (85.1)	632/773 (81.8)
HGBL all with double-/triple-hit lymphoma	41/391 (10.5)	24/382 (6.3)	65/773 (8.4)
Other confirmed lymphoma subtype*	43/391 (11.0)	33/382 (8.6)	76/773 (9.8)
COO (per GEP; central assessment)			
ABC-like, n/N (%)	84/239 (35.1)	88/245 (35.9)	172/484 (35.5)
GCB-like, n/N (%)	131/239 (54.8)	117/245 (47.8)	248/484 (51.2)
Unclassified, n/N (%)	24/239 (10.0)	40/245 (16.3)	64/484 (13.2)
Results not available, n (%)	209 (46.7)	206 (45.7)	415 (46.2)

*Other lymphoma subtypes included: T-cell/histiocyte-rich LBCL; EBV-positive DLBCL; ALK-positive LBCL; HHV-8–positive DLBCL, NOS; DLBCL coexistent with either indolent FL or gastric or nongastric MALT lymphoma; HGBL, NOS; grade 3b FL; and 'other'.
aaIPI, age-adjusted IPI; ABC, activated B-cell; ALK, anaplastic lymphoma kinase; COO, cell of origin; DLBCL, diffuse large B-cell lymphoma; EBV, Epstein-Barr virus; ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; GCB, germinal center B-cell; GEP, gene expression profiling; HGBL, high-grade B-cell lymphoma; HHV, human herpes virus; IPI, International Prognostic Index; ITT, intention-to-treat; LBCL, large B-cell lymphoma; Len, lenalidomide; MALT, mucosa-associated lymphoid tissue; NOS, not otherwise specified; Q, quartile; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone or prednisolone; Tafa, tafasitamab.

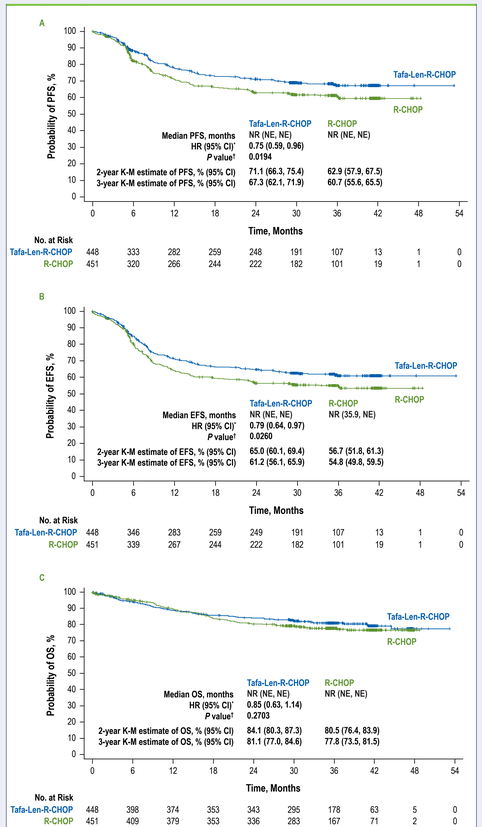
Relative Dose Intensities

- Median relative dose intensities (RDI) for each of the R-CHOP components across the 6 cycles of treatment were high, and were the same in both groups (100%) for all R-CHOP components, except vincristine (RDI ≥92.9% in the Tafa-Len-R-CHOP group and ≥92.1% in the R-CHOP group)

Efficacy

- At a median follow-up of 35.2 months, Tafa-Len-R-CHOP significantly improved investigator-assessed PFS vs R-CHOP (hazard ratio [HR] 0.75 [95% confidence interval {CI} 0.59, 0.96]; *P*=0.0194) **(Figure 2A)**
  - There was an 8.2% difference in 2-year PFS rate between the Tafa-Len-R-CHOP (71.1% [95% CI 66.3, 75.4]) and R-CHOP groups (62.9% [95% CI 57.9, 67.5])
- With median follow-up of 35.4 months, investigator-assessed event-free survival (EFS) was significantly improved with Tafa-Len-R-CHOP vs R-CHOP (HR 0.79 [95% CI 0.64, 0.97]; *P*=0.0260) **(Figure 2B)**
  - 2-year EFS rates were 65.0% (95% CI 60.1, 69.4) with Tafa-Len-R-CHOP and 56.7% (95% CI 51.8, 61.3) with R-CHOP
- 177 deaths had occurred at the primary PFS analysis
  - With a median follow-up of 35.9 months, interim analysis of overall survival demonstrated a positive trend in favor of Tafa-Len-R-CHOP (HR 0.85 [95% CI 0.63, 1.14]; *P*=0.2703 **(Figure 2C)**

Figure 2. Investigator-Assessed PFS (A), Investigator-Assessed EFS (B), and OS (C) (ITT Population)



*Calculated using a stratified Cox proportional hazards model. †Calculated using a stratified log-rank test.
CI, confidence interval; EFS, event-free survival; HR, hazard ratio; ITT, intention-to-treat; K-M, Kaplan-Meier; Len, lenalidomide; NE, not evaluable; NR, not reached; OS, overall survival; PFS, progression-free survival; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone or prednisolone; Tafa, tafasitamab.

- ORR (odds ratio [OR] 1.29 [95% CI 0.94, 1.78]; *P*=0.1201) and PET-negative complete response rate (OR 1.00 [95% CI 0.76, 1.31]; *P*=0.9873) were similar between treatment arms at EOT **(Table 2)**

Table 2. Investigator-Assessed Objective Response Rate (ITT Population)

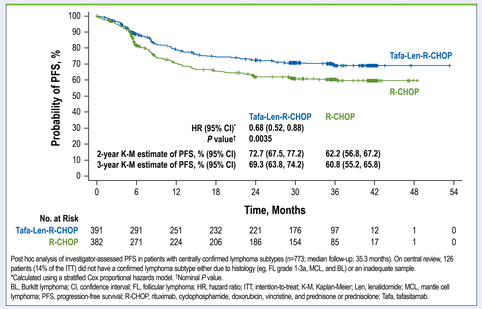
n (%), Unless Otherwise Stated	Tafa-Len-R-CHOP (n=448)	R-CHOP (n=451)
Objective response rate (95% CI)*,†	**80.4** (76.4, 83.9)	**76.1** (71.8, 79.9)
Odds ratio (95% CI)‡	**1.29 (0.94, 1.78)**	
Nominal *P* value§	**0.1201**	
Complete response (PET-negative CR) (95% CI)†	**65.2** (60.6, 69.6)	**65.2** (60.6, 69.6)
Odds ratio (95% CI)‡	**1.00 (0.76, 1.31)**	
Nominal *P* value§	**0.9873**	
Partial response	68 (15.2)	49 (10.9)
Stable disease	2 (0.4)	5 (1.1)
Relapsed or progressive disease	28 (6.3)	50 (11.1)
Not evaluable	58 (12.9)	53 (11.8)

*Objective response rate was defined as the proportion of patients who achieved a CR or PR per Lugano 2014 criteria at EOT. †95% CI calculated using the Clopper-Pearson exact method. ‡95% CI calculated using the Wald method. §Calculated using a stratified Cochran–Mantel–Haenszel test.
CI, confidence interval; CR, complete response; EOT, end of treatment; ITT, intention-to-treat; Len, lenalidomide; PET, positron emission tomography; PR, partial response; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone or prednisolone; Tafa, tafasitamab.

Post Hoc Analysis of Patients With Centrally Confirmed Lymphoma Subtypes

- In a post hoc analysis of patients with centrally confirmed lymphoma subtypes (n=773), the HR for PFS improved (HR 0.68 [95% CI 0.52, 0.88]) with Tafa-Len-R-CHOP (n=391) vs R-CHOP (n=382), with 2-year PFS rates of 72.7% vs 62.2% and 3-year PFS rates of 69.3% vs 60.8%, respectively **(Figure 3)**

Figure 3. Investigator-Assessed PFS in Centrally Confirmed Lymphoma Subtypes

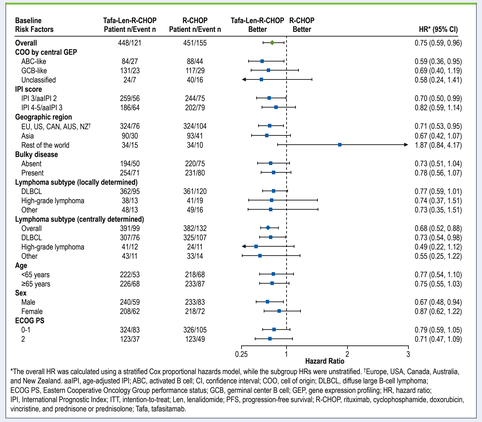


Post hoc analysis of investigator-assessed PFS in patients with centrally confirmed lymphoma subtypes (n=773; median follow-up: 35.3 months). †On central review; 126 patients (14% of the ITT) did not have a confirmed lymphoma subtype either due to histology (eg, FL grade 1-3a, MCL, and BL) or an inadequate sample. *Calculated using a stratified Cox proportional hazards model. †Nominal *P* value.
BL, Burkitt lymphoma; CI, confidence interval; FL, follicular lymphoma; HR, hazard ratio; ITT, intention-to-treat; K-M, Kaplan-Meier; Len, lenalidomide; MCL, mantle cell lymphoma; PFS, progression-free survival; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone or prednisolone; Tafa, tafasitamab.

Predefined Subgroup Analysis

- In a predefined subgroup analysis, consistent trends were observed toward PFS benefit, including in activated B-cell (ABC)– and germinal center B-cell (GCB)–like COO subtypes per central GEP **(Figure 4)**

Figure 4. Subgroup Analysis of Investigator-Assessed PFS (ITT Population)



*The overall HR was calculated using a stratified Cox proportional hazards model, while the subgroup HRs were unstratified. †Europe, USA, Canada, Australia, and New Zealand. aaIPI, age-adjusted IPI; ABC, activated B cell; CI, confidence interval; COO, cell of origin; DLBCL, diffuse large B-cell lymphoma; ECOG PS, Eastern Cooperative Oncology Group performance status; GCB, germinal center B cell; GEP, gene expression profiling; HR, hazard ratio; IPI, International Prognostic Index; ITT, intention-to-treat; Len, lenalidomide; PFS, progression-free survival; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone or prednisolone; Tafa, tafasitamab.

Exploratory Analyses

- The rate of MRD negativity at EOT was higher with Tafa-Len-R-CHOP vs R-CHOP (81.3% vs 66.7%) **(Table 3)**
- At relapse, all patients in the Tafa-Len-R-CHOP arm with B-cell lymphoma detected in biopsy tissue were CD19 positive (14/14) **(Table 3)**

Table 3. Exploratory Analyses (ITT Population)

	Tafa-Len-R-CHOP (n=448)	R-CHOP (n=451)
MRD*		
MRD tested (baseline and EOT), n	336	349
MRD evaluable (baseline positive, EOT positive/negative),† n	304	315
Negative status at EOT, n (%) 95% CI	**247 (81.3)** (76.4, 85.5)	**210 (66.7)** (61.2, 71.9)
CD19 expression		
Total biopsy samples at relapse, n	15	25
B-cell lymphoma cells detected in relapse biopsy,‡ n	14	24
CD19-positive, n/N (%)	**14/14 (100)**	**23/24 (95.8)**

*MRD-negativity threshold was defined for each sample as the minimum number of required genetic reads divided by the total sequencing reads (based on the 95th percentile, the lower limit of detection was ≤10⁻⁶). †Samples failed quality check: Tafa-Len-R-CHOP, n=7; R-CHOP, n=7. Samples with no tumor marker identified or negative at baseline: Tafa-Len-R-CHOP, n=25; R-CHOP, n=27. ‡2 patients (Tafa-Len-R-CHOP, n=1; R-CHOP, n=1) had no lymphoma present in relapse biopsies. 1 patient (R-CHOP arm) had indolent B-cell NHL in the biopsy at relapse. CD, cluster of differentiation; CI, confidence interval; EOT, end of treatment; ITT, intention-to-treat; Len, lenalidomide; MRD, minimal residual disease; NHL, non-Hodgkin lymphoma; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone or prednisolone; Tafa, tafasitamab.

Safety and Tolerability

- Incidence of any-grade treatment-emergent adverse events (TEAEs) were similar between the Tafa-Len-R-CHOP and R-CHOP groups (98.6% vs 97.1%) **(Table 4)**
  - More grade ≥3 TEAEs occurred with Tafa-Len-R-CHOP vs R-CHOP (86.7% vs 76.1%); the most common were related to cytopenias
  - Rates of serious febrile neutropenia were 13.3% with Tafa-Len-R-CHOP and 9.8% with R-CHOP
- TEAEs leading to discontinuation of all study drugs occurred in 5.2% vs 5.4% of patients in the Tafa-Len-R-CHOP vs R-CHOP groups, respectively
- Fatal TEAEs were predominantly balanced with Tafa-Len-R-CHOP (5.9%) and R-CHOP (3.8%); exceptions included higher rates of COVID-19 (7 [1.6%] vs 2 [0.4%]) and sepsis (7 [1.6%] vs 3 [0.7%]) with Tafa-Len-R-CHOP vs R-CHOP
- Overall, 82 (18.5%) patients died in the Tafa-Len-R-CHOP and 97 (21.7%) in the R-CHOP groups

Table 4. Most Frequent (≥12% in Any Group) and Grade ≥3 TEAEs (Safety Population)

	Tafa-Len-R-CHOP (n=443)		R-CHOP (n=447)	
Preferred Term, n (%)	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Neutropenia	313 (70.7)	306 (69.1)	267 (59.7)	259 (57.9)
Anemia	205 (46.3)	105 (23.7)	154 (34.5)	73 (16.3)
Peripheral neuropathy*	180 (40.6)	13 (2.9)	175 (39.1)	7 (1.6)
Thrombocytopenia	172 (38.8)	120 (27.1)	119 (26.6)	62 (13.9)
Constipation	152 (34.3)	0 (0)	126 (28.2)	0 (0)
Nausea	117 (26.4)	8 (1.8)	140 (31.3)	5 (1.1)
Diarrhea	109 (24.6)	12 (2.7)	74 (16.6)	6 (1.3)
Hypokalemia	96 (21.7)	33 (7.4)	65 (14.5)	18 (4.0)
Fatigue	95 (21.4)	9 (2.0)	86 (19.2)	8 (1.8)
COVID-19	90 (20.3)	20 (4.5)	104 (23.3)	15 (3.4)
Leukopenia	82 (18.5)	65 (14.7)	57 (12.8)	49 (11.0)
Pyrexia	82 (18.5)	4 (0.9)	54 (12.1)	2 (0.4)
Febrile neutropenia	74 (16.7)	73 (16.5)	57 (12.8)	57 (12.8)
Infusion-related reaction	71 (16.0)	3 (0.7)	50 (11.2)	1 (0.2)
Asthenia	49 (11.1)	7 (1.6)	54 (12.1)	5 (1.1)
Insomnia	48 (10.8)	2 (0.5)	57 (12.8)	1 (0.2)

TEAEs are Medical Dictionary for Regulatory Activities, version 27.1, Preferred Terms.
*Includes standard organ class group of preferred terms.
COVID-19, coronavirus disease 2019; Len, lenalidomide; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone or prednisolone; Tafa, tafasitamab; TEAE, treatment-emergent adverse event.

Conclusions

- **Tafa-Len-R-CHOP significantly prolonged PFS vs R-CHOP (HR 0.75; 2-year PFS rate, Δ=8.2%) in patients with previously untreated high-risk DLBCL and HGBL**
- **Point estimates suggested trends toward PFS advantage in key prespecified subgroup analyses**
- **Tafa-Len-R-CHOP improved MRD-negativity rate at EOT and CD19 expression was maintained at relapse**
- **The incremental safety events observed with Tafa-Len-R-CHOP were well managed and did not impact delivery of the R-CHOP backbone**
- **The results support the use of Tafa-Len-R-CHOP as a potential new standard first-line treatment for patients with high-risk DLBCL or HGBL, regardless of COO**

Disclosures

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