Outcomes From the Phase 3 inMIND Study of Tafasitamab Plus Lenalidomide and Rituximab for Patients With Relapsed/Refractory Follicular Lymphoma

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Disclosure of Potential Conflicts of Interest

Sehn: has served on advisory boards for AbbVie, Acerta, Apobiologix, AstraZeneca, Celgene, Debiopharm, Genentech, Genmab, Gilead Sciences, Incyte Corporation, Janssen, Karyopharm Therapeutics, Kite, Lundbeck, Merck, MorphoSys, Novartis, Sandoz, Takeda, TG Therapeutics, Verastem Oncology; served as an advisor and received research grants from Teva; served on advisory boards and speakers' bureau for Roche and Seattle Genetics

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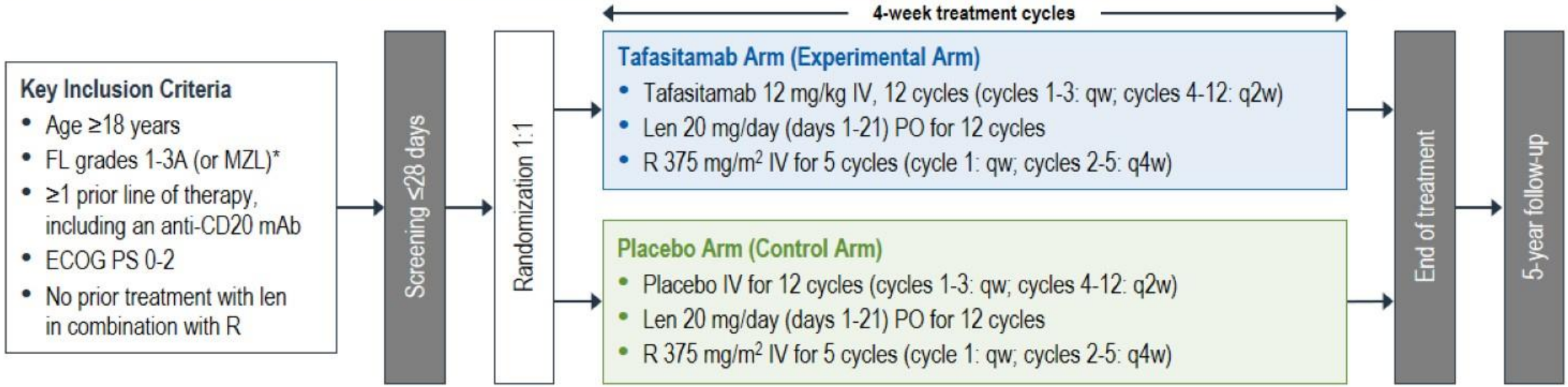
Background

- Most patients with follicular lymphoma (FL) experience relapsed or refractory disease (R/R) and need multiple lines of therapy
  - Chemoimmunotherapy is often used frontline but yields shorter remissions with each treatment
  - Immunotherapy options are now preferred in the R/R setting, but improved durability is needed
- Lenalidomide (len) + rituximab (R) is approved for R/R FL based on the AUGMENT study[1]
- Tafasitamab, a CD19-targeted monoclonal antibody (mAb), induces direct cytotoxicity and enhances natural killer (NK) cell and macrophage immune-mediated mechanisms
  - Tafasitamab + len is approved for patients with transplant-ineligible R/R diffuse large B-cell lymphoma (DLBCL) based on the L-MIND study[2]

- **inMIND** (NCT04680052) study evaluated the efficacy and safety of adding tafasitamab to len + R in patients with R/R FL or marginal zone lymphoma (MZL)
  - Based on results from inMIND, tafasitamab + len + R has been approved by the US FDA for adult patients with R/R FL[3]
- Here we present overall outcomes and results of exploratory and post hoc analyses

1. Leonard JP, et al. *J Clin Oncol*. 2019;37:1188-1899. **2.** Salles G, et al. *Lancet Oncol*. 2020;21:978-988. **3.** FDA approves tafasitamab-cxix for relapsed or refractory follicular lymphoma | FDA

inMIND: Phase 3, Double-Blind, Placebo-Controlled, International, Multicenter Randomized Study



Stratification Factors (Patients With FL)

- POD24
- Refractoriness to prior anti-CD20 mAb therapy
- Number of prior lines of therapy (1 or ≥2)

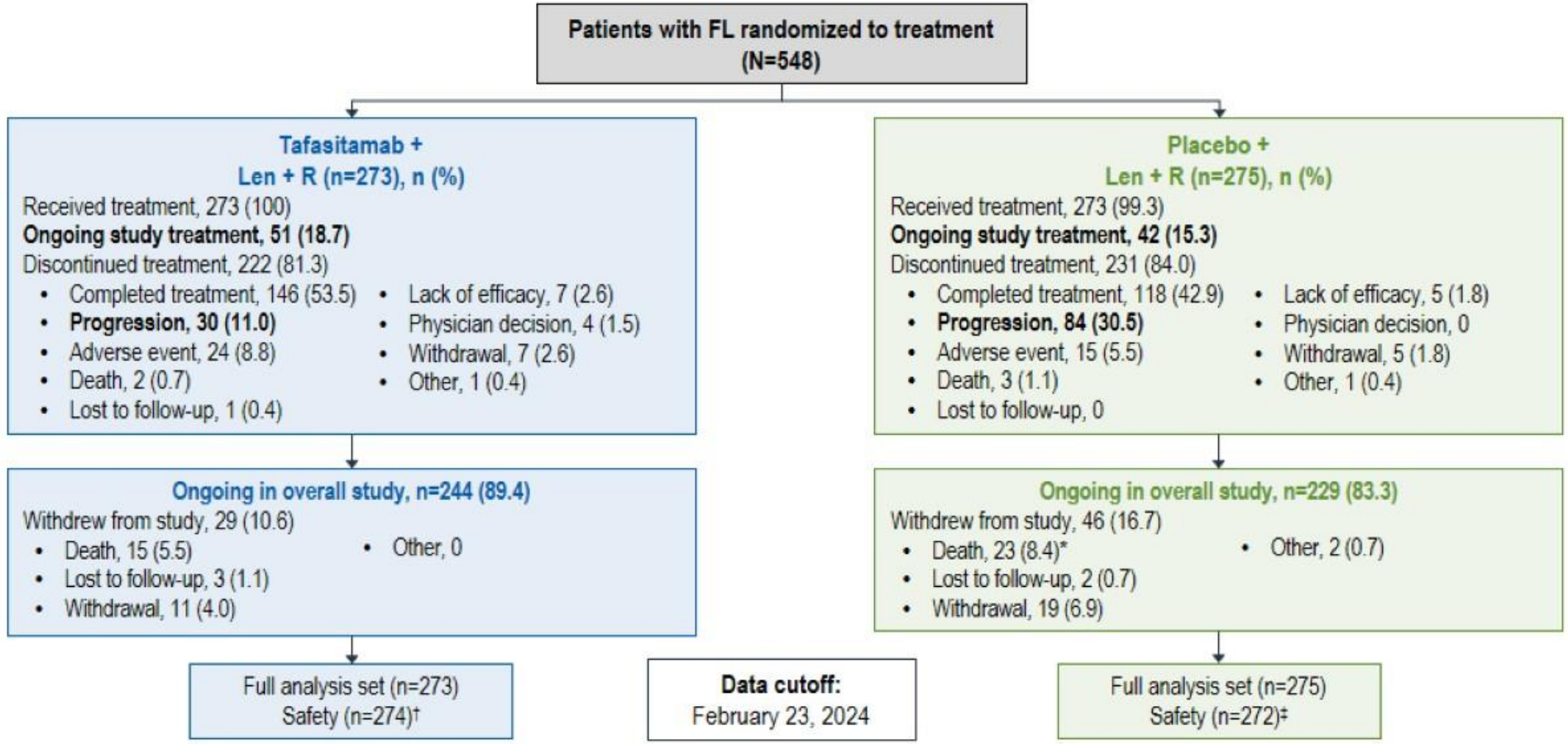
Study Endpoints in FL Population (Investigator Assessed Unless Specified)

- **Primary study endpoint:** PFS
- **Key secondary:** PET-CR rate in the FDG-avid population, OS
- **Select other secondary:** PFS by IRC, ORR, DOR, safety, QoL, MRD
- **Exploratory:** TTNT, B-cell recovery, Ig levels, CD19 expression

- Powered to assess PFS in the FL population, triggered when 174 investigator-assessed events occurred
- OS analysis planned after 5 years of follow-up

*Limited number of patients with MZL were enrolled but the study was not powered for this population; data for patients with MZL will be presented separately. DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FDG, fluorodeoxyglucose; FL, follicular lymphoma; Ig, immunoglobulin; IRC, independent review committee; IV, intravenous; len, lenalidomide; mAb, monoclonal antibody; MRD, minimal residual disease; MZL, marginal zone lymphoma; ORR, overall response rate; OS, overall survival; PET-CR, positron emission tomography-complete response; PFS, progression-free survival; PO, orally; POD24, disease progression within 24 months of initial diagnosis; QoL, quality of life; qw, weekly; q2w, every 2 weeks; q4w, every 4 weeks; R, rituximab; TTNT, time to next treatment.

Patient Disposition



- At primary analysis, median number of cycles received was 12 with tafasitamab and 11 with placebo

*Death for 1 patient was reported but not recorded in the end-of-study form. †One patient randomized to the placebo + len + R group is included in the tafasitamab + len + R safety population because the patient erroneously received tafasitamab. ‡Three patients randomized to the placebo + len + R group are not included in the safety population because they erroneously received tafasitamab (n=1), or did not receive any study treatment due to confirmation of R hypersensitivity (n=1), or the patient withdrew from the study (n=1). FL, follicular lymphoma; Len, lenalidomide; R, rituximab.

Baseline Characteristics

Variable	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)	Total (N=548)
Median age, years (range)	64.0 (36, 88)	64.0 (31, 85)	64.0 (31, 88)
≥75, n (%)	54 (19.8)	54 (19.6)	108 (19.7)
Male sex, n (%)	150 (54.9)	149 (54.2)	299 (54.6)
Median time since initial diagnosis of FL, years (range)	5.2 (0, 34)	5.5 (1, 33)	5.3 (0, 34)
ECOG PS at screening, n (%)			
0	181 (66.3)	192 (69.8)	373 (68.1)
1-2	92 (33.7)	83 (30.2)	175 (31.9)
Bone marrow involvement, n (%)			
Yes	88 (32.2)	91 (33.1)	179 (32.7)
No	169 (61.9)	162 (58.9)	331 (60.4)
Unknown/Missing	16 (5.9)	22 (8.0)	38 (6.9)
Ann Arbor stage, n (%)			
I or II	52 (19.0)	50 (18.2)	102 (18.6)
III or IV	221 (81.0)	225 (81.8)	446 (81.4)
FL grade, n (%)			
1 or 2	203 (74.4)	203 (73.8)	406 (74.1)
3A	67 (24.5)	71 (25.8)	138 (25.2)
B symptoms, n (%)	63 (23.1)	67 (24.4)	130 (23.7)
FLIPI score, n (%)			
0-1	57 (20.9)	57 (20.7)	114 (20.8)
2	79 (28.9)	67 (24.4)	146 (26.6)
3-5	137 (50.2)	150 (54.5)	287 (52.4)
GELF criteria, n (%)	222 (81.3)	232 (84.4)	454 (82.8)
FL diagnosis confirmed by central pathology, n (%)	256 (93.8)	251 (90.5)	507 (92.2)

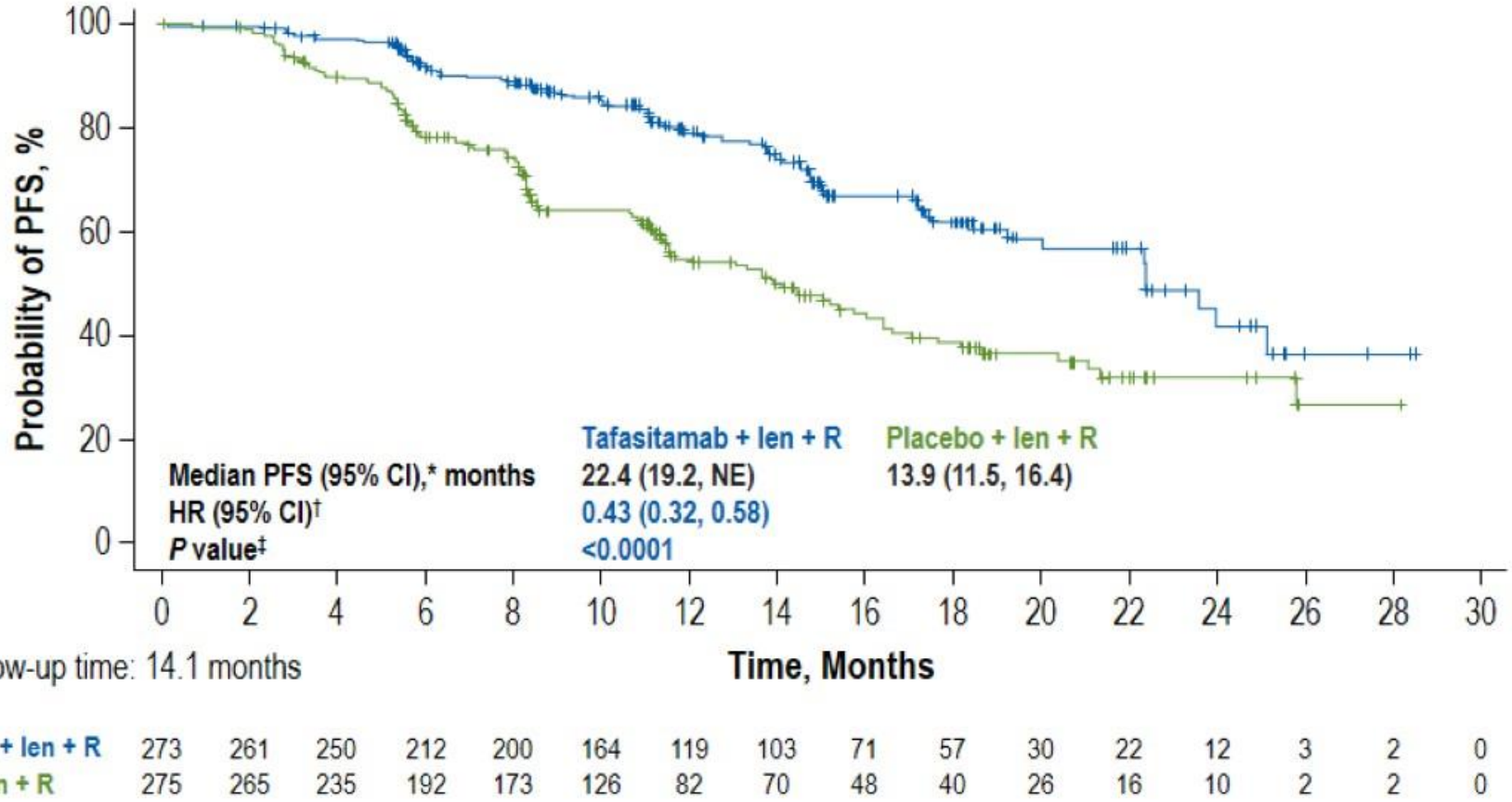
ITT population. ECOG PS, Eastern Cooperative Oncology Group performance status; FL, follicular lymphoma; FLIPI, Follicular Lymphoma International Prognostic Index; GELF, Groupe d'Etude des Lymphomes Folliculaires; ITT, intent-to-treat; Len, lenalidomide; R, rituximab.

Treatment History

Variable	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)	Total (N=548)
Median number of prior lines of therapy (range)	1.0 (1, 7)	1.0 (1, 10)	1.0 (1, 10)
Number of prior lines of therapy, n (%)			
1	147 (53.8)	153 (55.6)	300 (54.7)
2	66 (24.2)	71 (25.8)	137 (25.0)
3	39 (14.3)	30 (10.9)	69 (12.6)
≥4	21 (7.7)	21 (7.6)	42 (7.7)
Prior systemic anti-cancer treatment regimens, n (%)			
Anthracyclines	161 (59.0)	167 (60.7)	328 (59.9)
Anti-CD20 plus CHOP	151 (55.3)	161 (58.5)	312 (56.9)
Bendamustine alone or in combination	114 (41.8)	101 (36.7)	215 (39.2)
Anti-CD20 monotherapy	54 (19.8)	51 (18.5)	105 (19.2)
Anti-CD20 plus CVP	30 (11.0)	43 (15.6)	73 (13.3)
Chemotherapy plus ASCT	19 (7.0)	23 (8.4)	42 (7.7)
Time since last anti-lymphoma therapy, n (%)			
≤2 years	147 (53.8)	157 (57.1)	304 (55.5)
>2 years	126 (46.2)	118 (42.9)	244 (44.5)
POD24, n (%)	85 (31.1)	88 (32.0)	173 (31.6)
Relapsed/refractory status to last therapy, n (%)			
Relapsed	148 (54.2)	164 (59.6)	312 (56.9)
Refractory	112 (41.0)	97 (35.2)	209 (38.1)
Undetermined	13 (4.8)	14 (5.1)	27 (4.9)
Refractory to prior anti-CD20 therapy, n (%)	118 (43.2)	115 (41.8)	233 (42.5)

ITT population. ASCT, autologous stem cell transplant; CHOP, cyclophosphamide, doxorubicin, vincristine, prednisone; CVP, cyclophosphamide, vincristine, prednisone; ITT, intent-to-treat; Len, lenalidomide; POD24, disease progression within 24 months of initial diagnosis; R, rituximab.

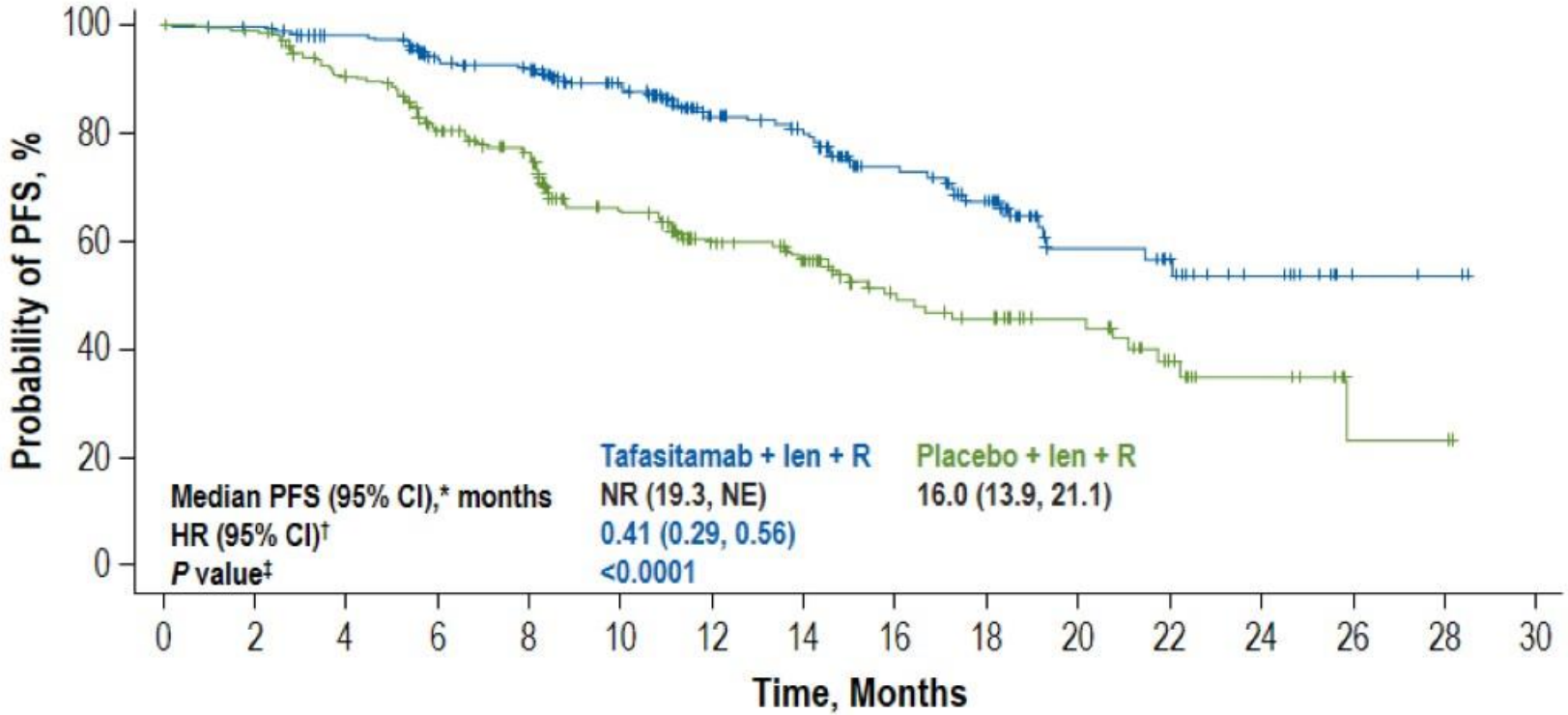
Primary Endpoint: PFS by Investigator Assessment



Significant improvement in PFS was observed with tafasitamab

ITT population. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Stratified log-rank test with a 2-sided significance level of 5%. CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; Len, lenalidomide; NE, not evaluable; PFS, progression-free survival; R, rituximab.

PFS by Independent Review Committee

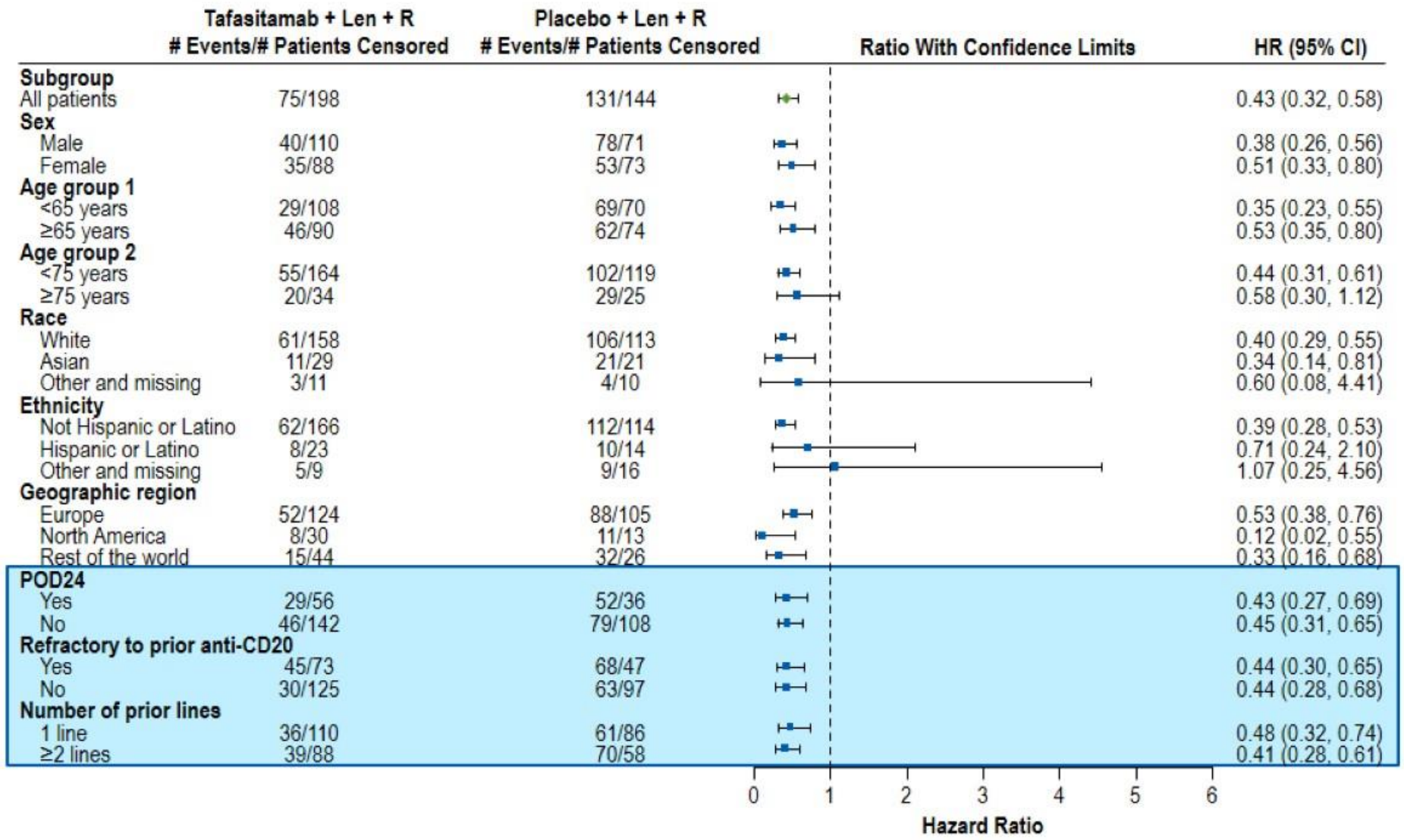


No. at Risk															
Tafasitamab + len + R	273	260	246	210	200	162	113	98	72	58	28	20	12	3	2	0
Placebo + len + R	275	260	230	193	170	120	79	67	44	38	26	15	8	2	2	0

Significant PFS benefit was confirmed by independent review committee

ITT population. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Nominal *P* value; stratified log-rank test with a 2-sided significance level of 5%.
CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; Len, lenalidomide; NE, not evaluable; NR, not reached; PFS, progression-free survival; R, rituximab.

Prespecified Subgroup Analysis of PFS



ITT population. Analysis by investigator assessment. CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; Len, lenalidomide; PFS, progression-free survival; POD24, progression of disease within 24 months; R, rituximab.

PFS by Prior Therapy and Baseline Risk

PFS by Prior Systemic Therapy	Tafasitamab + Len + R	Placebo + Len + R
Prior bendamustine,* n	114	101
Median PFS (95% CI), months	20.0 (15.0, 23.6)	11.4 (8.2, 14.5)
Hazard ratio (95% CI)	**0.42 (0.27, 0.65)**	
Prior anti-CD20 monotherapy,* n	54	51
Median PFS (95% CI), months	NR (17.1, NE)	14.5 (10.8, NE)
Hazard ratio (95% CI)	**0.46 (0.21, 1.00)**	
Anti-CD20 as only prior systemic therapy, n	26	19
Median PFS (95% CI), months	NR (NE, NE)	16.4 (10.6, NE)
Hazard ratio (95% CI)	**0.21 (0.04, 1.07)**	
Prior anti-CD20 plus CHOP,* n	151	161
Median PFS (95% CI), months	22.4 (17.5, NE)	12.0 (8.6, 15.2)
Hazard ratio (95% CI)	**0.37 (0.25, 0.55)**	
Prior anti-CD20 plus CVP,* n	30	43
Median PFS (95% CI), months	25.1 (11.1, NE)	17.6 (11.7, NE)
Hazard ratio (95% CI)	**0.70 (0.30, 1.64)**	

PFS by Baseline Characteristics	Tafasitamab + Len + R	Placebo + Len + R
Baseline FL grade 1 or 2, n	203	203
Median PFS (95% CI), months	22.4 (17.5, NE)	14.1 (11.4, 16.6)
Hazard ratio (95% CI)	**0.50 (0.36, 0.70)**	
Baseline FL grade 3A, n	67	71
Median PFS (95% CI), months	24.0 (18.5, NE)	13.9 (10.7, 18.2)
Hazard ratio (95% CI)	**0.32 (0.17, 0.61)**	
Baseline FLIPI score 0-2, n	136	124
Median PFS (95% CI), months	NR (22.4, NE)	16.6 (13.6, 25.8)
Hazard ratio (95% CI)	**0.40 (0.24, 0.66)**	
Baseline FLIPI score 3-5, n	137	150
Median PFS (95% CI), months	19.2 (14.8, 23.6)	11.2 (8.4, 15.2)
Hazard ratio (95% CI)	**0.43 (0.30, 0.62)**	

Benefit of tafasitamab observed regardless of patients' prior type of therapy or baseline disease characteristics

ITT population. *Regardless of treatment line. Patients could have received more than one line and type of therapy prior to receiving study treatment. CHOP, cyclophosphamide, doxorubicin hydrochloride, vincristine sulphate, and prednisone; CI, confidence interval; CHOP, cyclophosphamide, doxorubicin, vincristine, prednisone; CVP, cyclophosphamide, vincristine sulfate, and prednisone; FL, follicular lymphoma; FLIPI, Follicular Lymphoma International Prognostic Index; ITT, intent-to-treat; Len, lenalidomide; NE, not evaluable; NR, not reached; PFS, progression-free survival; R, rituximab.

PET-CR and ORR

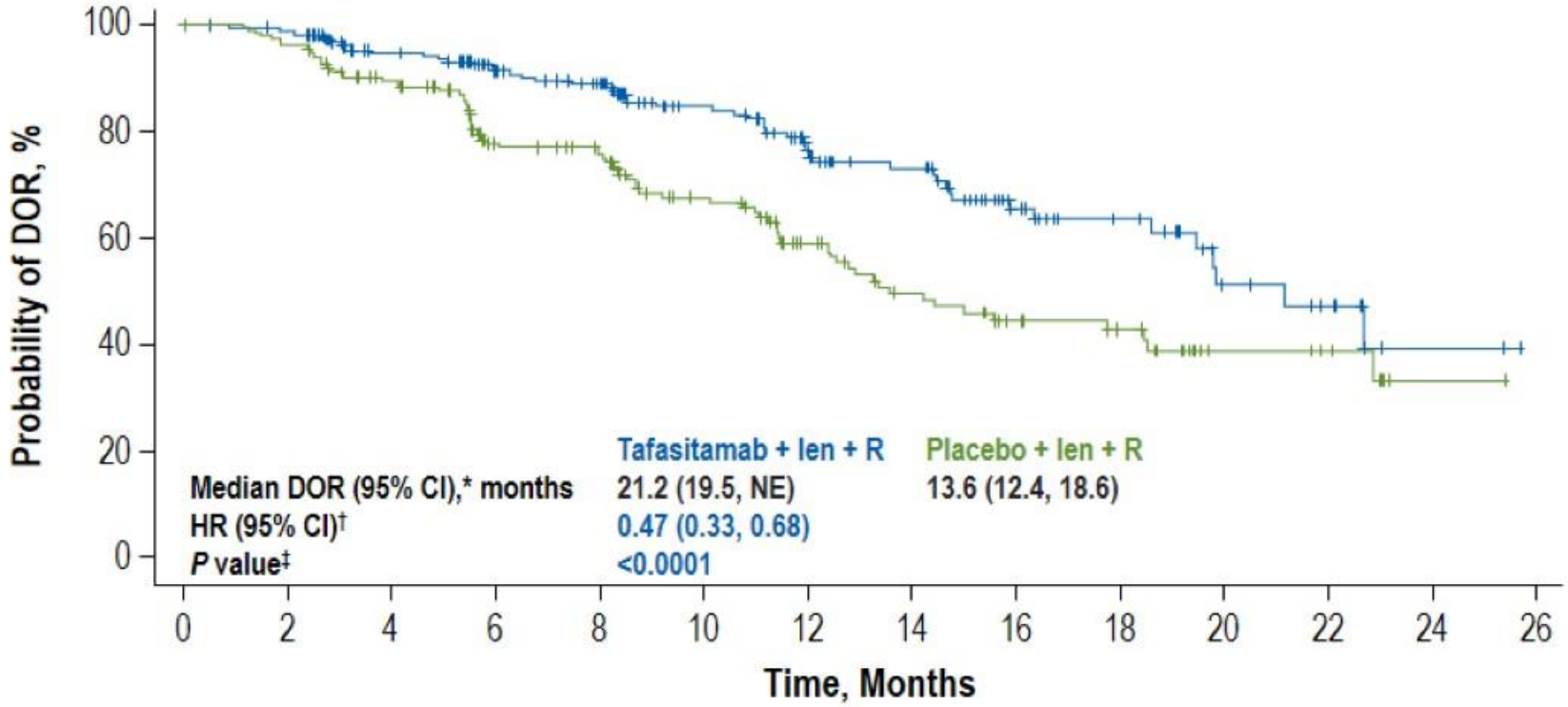
PET-CR (FDG-Avid Population)	Tafasitamab + Len + R	Placebo + Len + R
Patients with FDG-avid disease at baseline	251	254
Patients with postbaseline PET assessments, n (%)*	201/251 (80.1)	205/254 (80.7)
Best metabolic response based on PET,† n (%)		
CMR	124 (49.4)	101 (39.8)
PMR	37 (14.7)	39 (15.4)
NMR/SD	19 (7.6)	12 (4.7)
PMD	19 (7.6)	51 (20.1)
Not done	50 (19.9)	46 (19.3)
PET-CR rate,‡ % (95% CI)	**49.4** (43.1, 55.8)	**39.8** (33.7, 46.1)
Odds ratio (95% CI)	**1.5 (1.04, 2.13)**	
Nominal *P* value	**0.0286**	

ORR (ITT Population)	Tafasitamab + Len + R	Placebo + Len + R
Patients, n	273	275
Best overall response,** n (%)		
CR	142 (52.0)	112 (40.7)
PR	86 (31.5)	87 (31.6)
SD	28 (10.3)	46 (16.7)
PD	7 (2.6)	20 (7.3)
NE	2 (0.7)	0
Not done	8 (2.9)	10 (3.6)
ORR, % (95% CI)	**83.5** (78.6, 87.7)	**72.4** (66.7, 77.6)
Odds ratio (95% CI)	**2.0 (1.30, 3.02)**	
Nominal *P* value	**0.0014**	

Significant improvement in CMR rate and ORR was observed with tafasitamab

Analysis by investigator assessment. *Defined as having a Deauville score of 4 or 5 at baseline. †Two patients (0.8%) in both arms had PET after confirmed PD or new antilymphoma treatment initiation. ‡PET-CR rate defined as proportion of patients who achieved CMR at any time after start of treatment as per Lugano criteria in patients with FDG-avid disease at baseline, by PET-CR results only. **Per Lugano 2014 criteria. Complete response did not require bone marrow confirmation. CI, confidence interval; CMR, complete metabolic response; CR, complete response; FDG, fluorodeoxyglucose; ITT, intent-to-treat; Len, lenalidomide; NE, not evaluable; NMR, nonmetabolic response; ORR, overall response rate; PD, progressive disease; PET, positron emission tomography; PET-CR, positron emission tomography-complete response; PMD, progressive metabolic disease; PMR, partial metabolic response; PR, partial response; R, rituximab; SD, stable disease.

Duration of Response

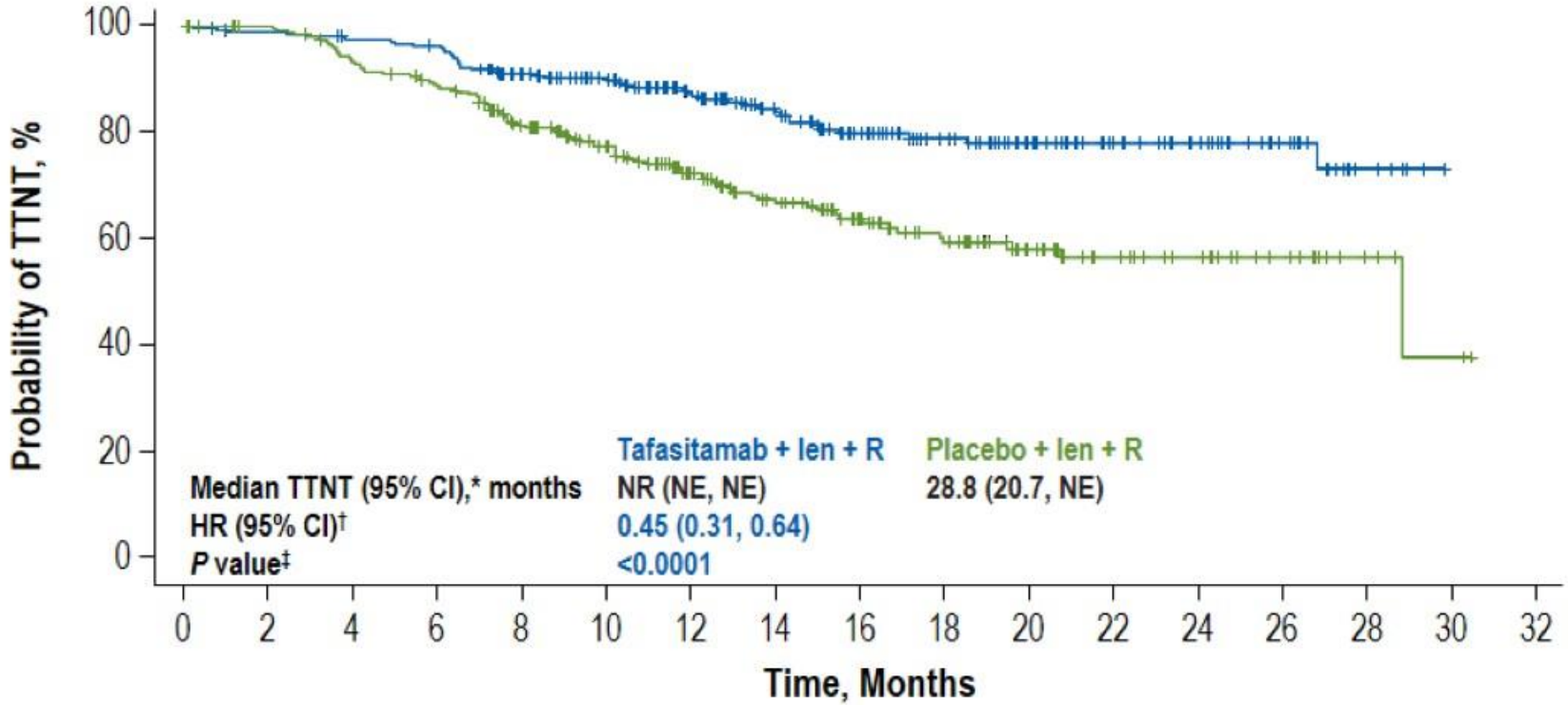


No. at Risk													
Tafasitamab + len + R	228	219	185	155	140	105	81	66	37	27	14	10	3	0
Placebo + len + R	199	188	163	115	106	75	54	40	29	22	10	8	2	0

Significant improvement in DOR was observed with tafasitamab

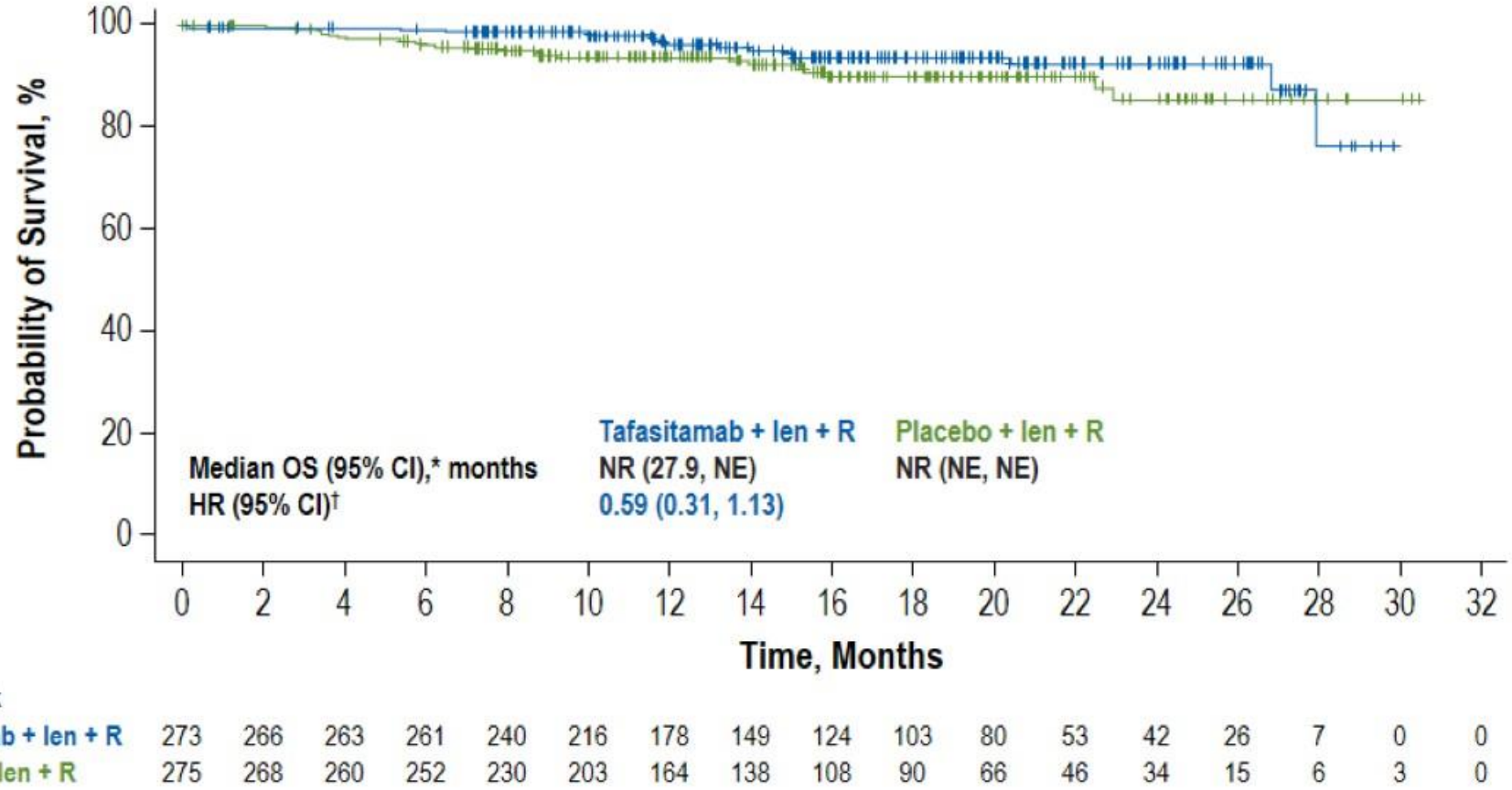
ITT population. Analysis by investigator assessment. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Nominal *P* value; stratified log-rank test with a 2-sided significance level of 5%. CI, confidence interval; DOR, duration of response; HR, hazard ratio; ITT, intent-to-treat; Len, lenalidomide; NE, not evaluable; R, rituximab.

Time to Next Treatment



ITT population. Analysis by investigator assessment. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. ‡Nominal *P* value; stratified log-rank test with a 2-sided significance level of 5%. CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; len, Lenalidomide; NE, not evaluable; NR, not reached; R, rituximab; TTNT, time to next treatment.

Overall Survival



- OS was tested only for futility at the time of the primary analysis
- After a median follow-up of 15.3 months, the futility threshold was not crossed and a positive trend was observed

ITT population. Analysis by investigator assessment. *Estimated using Kaplan-Meier method. †Estimated using a stratified Cox proportional hazard model. CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; Len, lenalidomide; NE, not evaluable; NR, not reached; OS, overall survival; R, rituximab.

Histological Transformation

Variable	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)
Patients with transformation into more aggressive histology,* n (%)	0 (0.0)	9 (3.3)
Rate of transformation into more aggressive histology (95% CI)	0.0 (0.0, 1.3)	3.3 (1.5, 6.1)
Median time to transformation (95% CI)†	NR (NE, NE)	NR (NE, NE)

ITT population (exploratory analysis). *Transformation of FL into more aggressive histology (eg, DLBCL) was defined as the appearance of diffuse areas of large-cell lymphoma cells within a lymphoma site as proven by a histological examination of a tumour biopsy at the time of disease progression. †Estimated using the Kaplan-Meier method.
CI, confidence interval; DLBCL, diffuse large B-cell lymphoma; NE, not evaluable; Len, lenalidomide; R, rituximab.

CD19 Expression[1]

- Central lab-assessment of CD19 expression in screening biopsy demonstrated:
  - 86% of patients had 100% CD19-positive cells
  - 14% of patients had a median of 50% CD19-positive cells, which included a range of 10%–85% and 2 CD19-negative patients in the placebo arm
- 23 out of 24 post-treatment samples where lymphoma was detected remained CD19-positive, including 7 out of 8 samples from patients who received tafasitamab + len + R
  - 1 sample from a patient who received tafasitamab + len + R and achieved a PR was CD19 negative (this patient had 80% CD19-negative tumour cells at screening)

CD19 Expression at End of Treatment or Follow-Up

Sample	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)
Total samples,* n	13	19
Lymphoma detected, n	8	16
CD19 positive,† n/N	7/8	16/16

1. Reinke S, et al. Presented at: European Hematology Association (EHA) Hybrid Congress 2025 (Poster PF1006) (*HemaSphere*. 2025;9[S1]:1435-1436)
*Data represent samples from patients with FL, except for 2 patients with MZL (1 per arm) enrolled in the inMIND study. †CD19 expression by IHC. FL, follicular lymphoma; IHC, immunohistochemistry; Len, lenalidomide; MZL, marginal zone lymphoma; PR, partial response; R, rituximab.

Most Frequent Any-Grade TEAEs (≥15% in Any Group)

Preferred Term, n (%)	Tafasitamab + Len + R (n=274)*	Placebo + Len + R (n=272)†	Total (n=546)
Any adverse event	272 (99.3)	270 (99.3)	542 (99.3)
Neutropenia	133 (48.5)	123 (45.2)	256 (46.9)
Diarrhea	103 (37.6)	77 (28.3)	180 (33.0)
COVID-19	86 (31.4)	64 (23.5)	150 (27.5)
Constipation	80 (29.2)	67 (24.6)	147 (26.9)
Rash	60 (21.9)	58 (21.3)	118 (21.6)
Fatigue	58 (21.2)	43 (15.8)	101 (18.5)
Cough	52 (19.0)	47 (17.3)	99 (18.1)
Pyrexia	52 (19.0)	44 (16.2)	96 (17.6)
Muscle spasms	49 (17.9)	49 (18.0)	98 (17.9)
Nausea	49 (17.9)	38 (14.0)	87 (15.9)
Infusion-related reaction	43 (15.7)	41 (15.1)	84 (15.4)
Thrombocytopenia	37 (13.5)	42 (15.4)	79 (14.5)
Pruritus	44 (16.1)	28 (10.3)	72 (13.2)

Safety population. *One patient randomized to the placebo + len + R group is included in the tafasitamab + len + R safety population because the patient erroneously received tafasitamab. †Three patients randomized to the placebo + len + R group are not included in the safety population because they erroneously received tafasitamab (n=1), or did not receive any study treatment due to confirmation of R hypersensitivity (n=1), or the patient withdrew from the study (n=1). COVID-19, coronavirus disease 2019; Len, lenalidomide; R, rituximab; TEAE, treatment-emergent adverse event.

Grade 3 or 4 TEAEs, Deaths, and Dose Modifications

Most Common Grade 3 or 4 TEAEs (≥5% in Any Group)

Preferred Term, n (%)	Tafasitamab + Len + R (n=274)*	Placebo + Len + R (n=272)†	Total (n=546)
Neutropenia	109 (39.8)	102 (37.5)	211 (38.6)
Pneumonia	23 (8.4)	14 (5.1)	37 (6.8)
Thrombocytopenia	17 (6.2)	20 (7.4)	37 (6.8)
Neutrophil count decreased	16 (5.8)	18 (6.6)	34 (6.2)
Anemia	12 (4.4)	16 (5.9)	28 (5.1)
COVID-19	16 (5.8)	6 (2.2)	22 (4.0)
COVID-19 pneumonia	13 (4.7)	3 (1.1)	16 (2.9)

- 15 patients (6%) in tafasitamab arm and 23 patients (9%) in placebo arm died during the study
  - Disease progression: 5 patients (2%) tafasitamab; 17 patients (6%) placebo
  - Fatal adverse events: 6 patients (2%) in each treatment arm (most commonly due to infection)

- Tafasitamab and placebo dose interruptions or discontinuations due to TEAEs were similar between treatment arms, n (%):
  - Dose delay or interruption due to TEAEs: 203 (74%) vs 190 (70%)
  - Discontinued study treatment due to TEAEs: 30 (11%) vs 18 (7%)
- Len discontinuations due to TEAEs were similar between tafasitamab and placebo arms, n (%):
  - 39 (14%) vs 31 (11%)
- Len dose reductions were similar between tafasitamab and placebo arms
  - Median relative dose intensity: 86% vs 87%

Safety population. *One patient randomized to the placebo + len + R group is included in the tafasitamab + len + R safety population because the patient erroneously received tafasitamab. †Three patients randomized to the placebo + len + R group are not included in the safety population because they erroneously received tafasitamab (n=1), or did not receive any study treatment due to confirmation of R hypersensitivity (n=1), or the patient withdrew from the study (n=1). COVID-19, coronavirus disease 2019; Len, lenalidomide; R, rituximab; TEAE, treatment-emergent adverse event.

Conclusions

- The inMIND phase 3 study met its primary endpoint of prolonging PFS in R/R FL
  - Addition of tafasitamab to lenalidomide and rituximab resulted in significant improvement in PFS, representing a 57% reduction in risk of progression, relapse, or death
  - Benefit was observed in all prespecified subgroups and regardless of baseline disease characteristics or prior systemic therapy received
- Although OS data are immature, a trend in favor of tafasitamab was observed
- The safety profile was manageable and consistent with expected toxicities with these agents
- This study is the first to validate the approach of combining 2 antibodies (anti-CD19 with anti-CD20) for treatment of FL
- Tafasitamab plus lenalidomide and rituximab can be administered in community as well as academic settings and represents a potential new standard of care for patients with R/R FL

FL, follicular lymphoma; mAb, monoclonal antibody; OS, overall survival; PFS, progression-free survival; POD24, disease progression within 24 months of initial diagnosis; R/R, relapsed or refractory.

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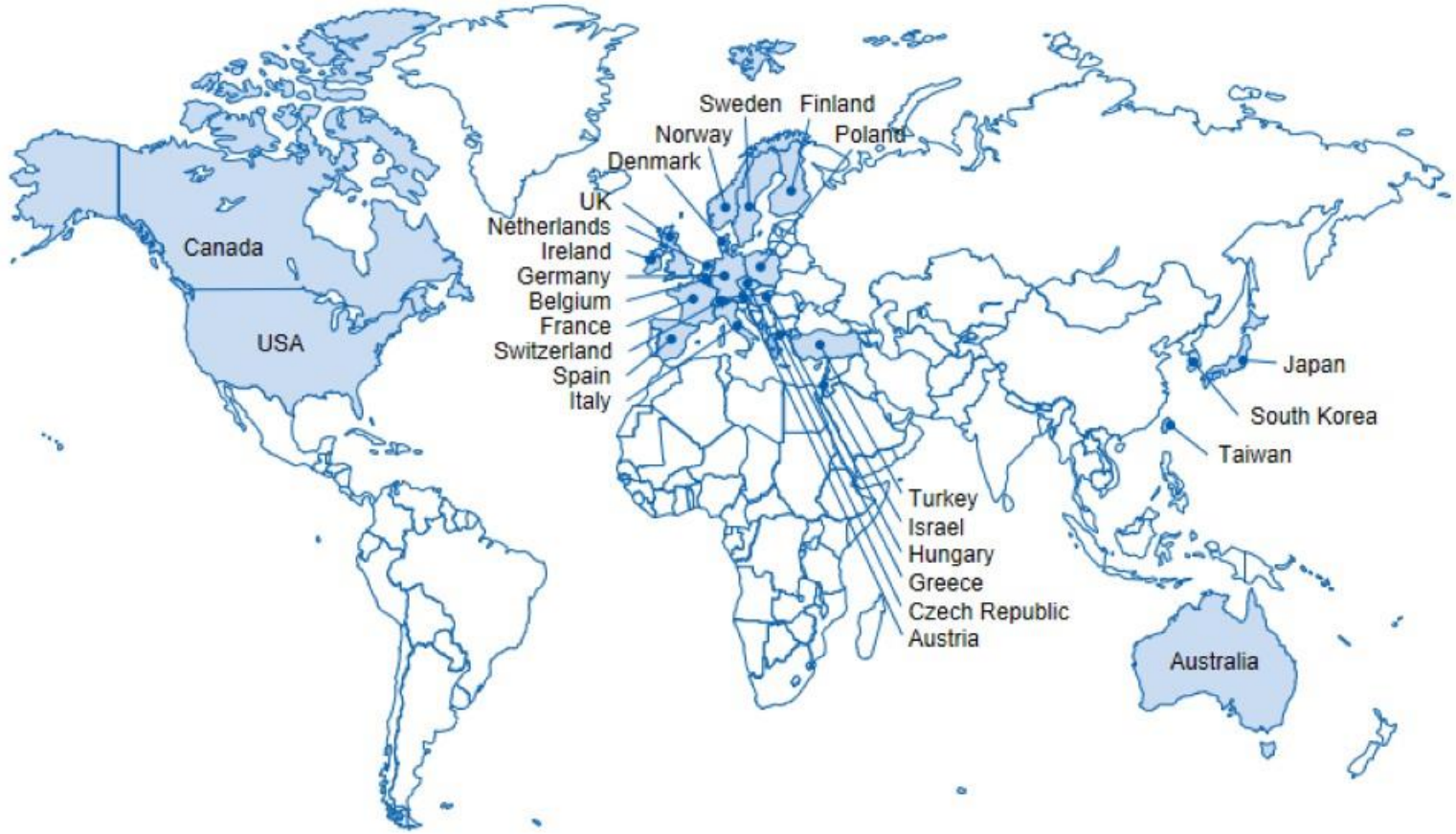

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