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Quality of Life Outcomes With Tafasitamab Plus Lenalidomide and Rituximab for Relapsed or Refractory Follicular Lymphoma: Results From a Phase 3, Double-Blind, Randomized, Placebo-Controlled, International, Multicenter Study (inMIND)

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Introduction

- Follicular lymphoma (FL) is the most common indolent non-Hodgkin lymphoma, accounting for 20%-25% of cases in developed countries[1,2]
- Despite high rates of long-term survival (77%-85% 10-year overall survival [OS]), FL is generally incurable, characterized by periods of remission and relapse[3,4]
- The global inMIND study reported a significant, clinically meaningful improvement in progression-free survival (PFS) with a 57% reduction in risk of progression, relapse, or death in patients with relapsed or refractory (R/R) FL when tafasitamab was added to lenalidomide (len) plus rituximab (tafasitamab + len + R) compared with placebo added to len plus R (placebo + len + R)[5]
  - The safety profile of the combination treatment was manageable and consistent with expected toxicities
  - Based on results from inMIND, tafasitamab + len + R has been approved by the US Food and Drug Administration for adult patients with R/R FL[6]
- Due to the indolent, chronic nature of FL, where patients may require multiple lines of treatment, collecting quality-of-life (QoL) data is important[7,8]
- Here, we report QoL data from patients with R/R FL enrolled in the inMIND study

Objectives

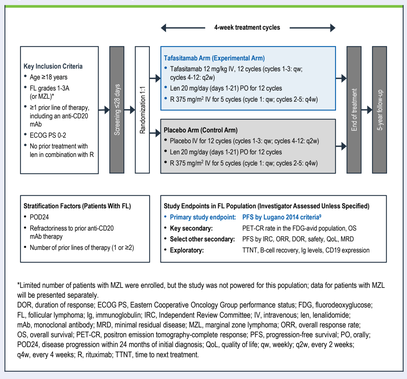
- To assess QoL outcomes, a prespecified secondary endpoint of inMIND
- To better understand the effects of adding tafasitamab to len + R and the benefit/risk profile of the treatment

Methods

inMIND Study Design and Treatment

- inMIND (NCT04680052) is a phase 3, double-blind, randomized, placebo-controlled, international, multicenter trial **(Figure 1)**

Figure 1. inMIND Study Design



*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.

- Eligible patients were randomized to receive tafasitamab + len + R (tafasitamab arm) or placebo + len + R (placebo arm) for up to 12×28-day cycles

Study Assessments

- Patients completed the following questionnaires at baseline, at day 1 of each cycle, and at the end of treatment (EOT):
  - European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-30 items (EORTC QLQ-C30), including the global health status/QoL scale, 5 functional scales (physical, role, emotional, cognitive, and social), 3 symptom scales (fatigue; presented), and 6 single items (eg, insomnia; not presented)
  - Functional Assessment of Cancer Therapy-Lymphoma (FACT-Lym), including well-being subscales such as physical, social/family, emotional, and functional (not presented), the FACT-Lymphoma subscale, the FACT-Lym trial outcome index, the FACT-G total score, and the FACT-Lym total score
  - 5-level EQ-5D (EQ-5D-5L) description system dimensions, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (not presented), and a visual analog scale (VAS)

Statistical Methods

- Completion rates were calculated as proportion of patients who received ≥1 study drug at the visit (or who had a record of a visit at EOT) that also had ≥1 QoL assessment at that time point
- Data were summarized using descriptive statistics, and change from baseline over time was plotted

Minimally Important Differences (MIDs)

- MID thresholds were applied to mean change from baseline scores over time to assess whether observed differences were clinically meaningful
- Lower limit of previously established MID ranges was used as a conservative threshold[10-14]

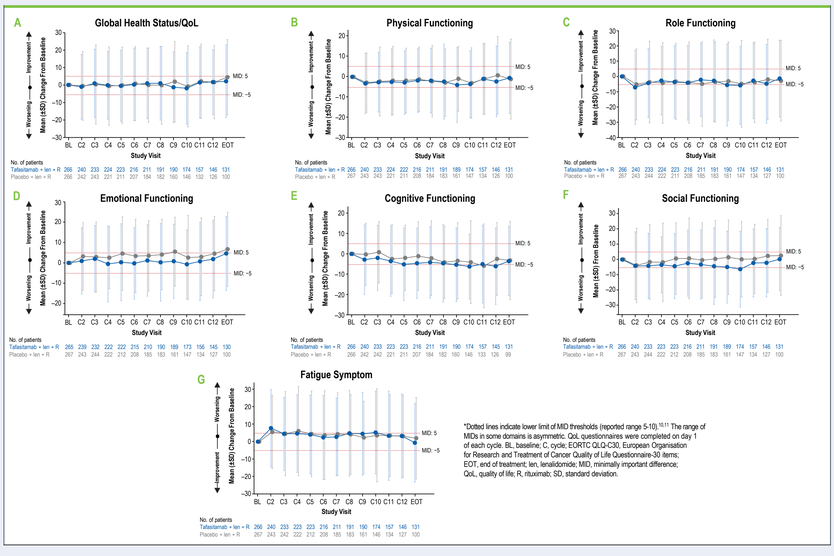
Results

Table 1. Questionnaire Completion Rates*

	EORTC QLQ-C30		FACT-Lym		EQ-5D-5L	
Time Point	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)	Tafasitamab + Len + R (n=273)	Placebo + Len + R (n=275)
Baseline	266/273 (**97**)	267/273 (**98**)	262/273 (**96**)	265/273 (**97**)	264/273 (**97**)	265/273 (**97**)
Cycle 2	243/258 (**94**)	248/264 (**94**)	238/258 (**92**)	243/264 (**92**)	239/258 (**93**)	244/264 (**92**)
Cycle 3	237/259 (**92**)	250/258 (**97**)	233/259 (**90**)	243/258 (**94**)	234/259 (**90**)	244/258 (**95**)
Cycle 4	226/246 (**92**)	227/239 (**95**)	225/246 (**92**)	219/239 (**92**)	226/246 (**92**)	220/239 (**92**)
Cycle 5	226/244 (**93**)	217/235 (**92**)	225/244 (**92**)	214/235 (**91**)	223/244 (**91**)	215/235 (**91**)
Cycle 6	220/236 (**93**)	212/222 (**95**)	219/236 (**93**)	208/222 (**94**)	218/236 (**92**)	209/222 (**94**)
Cycle 7	215/232 (**93**)	189/205 (**92**)	214/232 (**92**)	186/205 (**91**)	214/232 (**92**)	187/205 (**91**)
Cycle 8	195/218 (**89**)	188/198 (**95**)	195/218 (**89**)	185/198 (**93**)	194/218 (**89**)	184/198 (**93**)
Cycle 9	193/207 (**93**)	165/183 (**90**)	192/207 (**93**)	166/183 (**91**)	193/207 (**93**)	164/183 (**90**)
Cycle 10	176/187 (**94**)	150/160 (**94**)	175/187 (**94**)	148/160 (**93**)	176/187 (**94**)	147/160 (**92**)
Cycle 11	157/170 (**92**)	137/142 (**96**)	157/170 (**92**)	136/142 (**96**)	156/170 (**92**)	136/142 (**96**)
Cycle 12	146/157 (**93**)	131/135 (**97**)	145/157 (**92**)	129/135 (**96**)	146/157 (**93**)	131/135 (**97**)
EOT	102/116 (**88**)	132/145 (**91**)	101/116 (**87**)	133/145 (**92**)	103/116 (**89**)	133/145 (**92**)

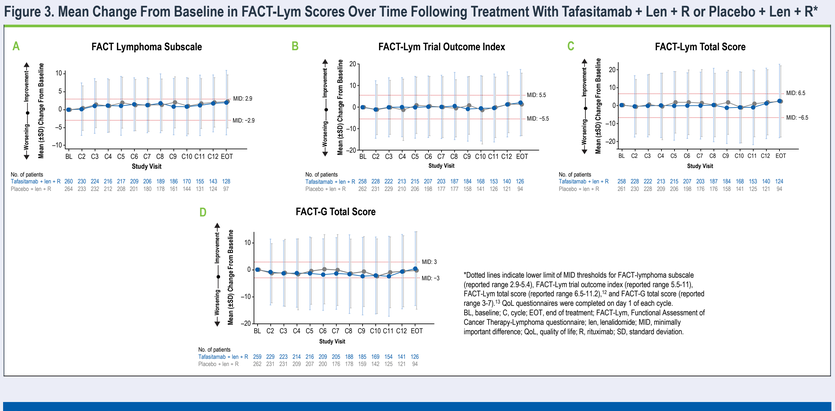
*Baseline to cycle 12 denominator: all patients who received ≥1 dose of any study drug at visit; EOT denominator: all patients who completed treatment with ≥1 recorded EOT visit were completed on day 1 of each cycle. EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-30 items; EOT, end of treatment; EQ-5D-5L, 5-level EQ-5D questionnaire; FACT-Lym, Functional Assessment of Cancer Therapy-Lymphoma questionnaire; len, lenalidomide; R, rituximab.

Figure 2. Mean Change From Baseline in EORTC QLQ-C30 Scores Over Time Following Treatment With Tafasitamab + Len + R or Placebo + Len + R*



*Dotted lines indicate lower limit of MID thresholds (reported range 5-10).[10,11] The range of MIDs in some domains is asymmetric. QoL questionnaires were completed on day 1 of each cycle. BL, baseline; C, cycle; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-30 items; EOT, end of treatment; len, lenalidomide; MID, minimally important difference; QoL, quality of life; R, rituximab; SD, standard deviation.

Figure 3. Mean Change From Baseline in FACT-Lym Scores Over Time Following Treatment With Tafasitamab + Len + R or Placebo + Len + R*



*Dotted lines indicate lower limit of MID thresholds for FACT-lymphoma subscale (reported range 2.9-5.4), FACT-Lym trial outcome index (reported range 5.5-11), FACT-Lym total score (reported range 6.5-11.2),[12] and FACT-G total score (reported range 3-7).[13] QoL questionnaires were completed on day 1 of each cycle. BL, baseline; C, cycle; EOT, end of treatment; FACT-Lym, Functional Assessment of Cancer Therapy-Lymphoma questionnaire; len, lenalidomide; MID, minimally important difference; QoL, quality of life; R, rituximab; SD, standard deviation.

Patients and Baseline Characteristics

- 548 patients with R/R FL were enrolled in inMIND: tafasitamab arm, 273; placebo arm, 275
- Baseline and demographic characteristics were similar between the 2 treatment arms[5]
  - Median age, 64 years (range, 31-88); male, 55%; FLIPI score 2-5, 79%; met Groupe d'Etude des Lymphomes Folliculaires (GELF) criteria, 83%
  - 45% had ≥2 prior lines, 32% had POD24 (within 24 months of initial diagnosis), 43% were refractory to prior anti-CD20 monoclonal antibody treatment

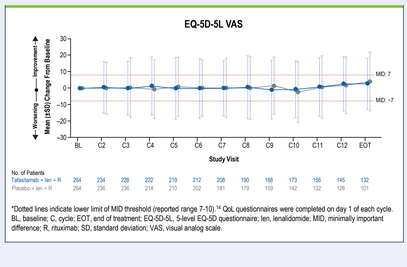
Questionnaire Completion Rates

- EORTC QLQ-C30, FACT-Lym, and EQ-5D-5L completion rates were high for both arms and similar from baseline through EOT **(Table 1)**
- Percentage of patients with ≥1 assessment at each time point by questionnaire were:
  - EORTC QLQ-C30: tafasitamab arm, ≥89%; placebo arm, ≥88%
  - FACT-Lym: tafasitamab arm, ≥89%; placebo arm, ≥87%
  - EQ-5D-5L: tafasitamab arm, ≥89%; placebo arm, ≥89%

EORTC QLQ-C30, FACT-Lym, and EQ-5D-5L Outcomes

- Changes from baseline in EORTC QLQ-C30 scores **(Figure 2)** and FACT-Lym scores **(Figure 3)** were generally similar between treatment arms from the start of treatment to EOT
- Change from baseline in EQ-5D-5L VAS **(Figure 4)** was also generally similar between treatment arms from the start of treatment to EOT

Figure 4. Mean Change From Baseline in EQ-5D-5L VAS Scores Over Time Following Treatment With Tafasitamab + Len + R or Placebo + Len + R*



*Dotted lines indicate lower limit of MID threshold (reported range 7-10).[14] QoL questionnaires were completed on day 1 of each cycle. BL, baseline; C, cycle; EOT, end of treatment; EQ-5D-5L, 5-level EQ-5D questionnaire; len, lenalidomide; MID, minimally important difference; R, rituximab; SD, standard deviation; VAS, visual analog scale.

Conclusions

- **QoL outcomes remained stable and were similar over time between the tafasitamab and placebo groups across all 3 questionnaires (EORTC QLQ-C30, FACT-Lym, and EQ-5D-5L), suggesting a limited impact on QoL. Furthermore, as there were no sustained changes exceeding MID thresholds, the magnitude of change is unlikely to be clinically meaningful**
- **These results suggest that the 57% reduction in risk of progression, relapse, or death observed in PFS in the tafasitamab + len + R arm of inMIND, was achieved without detriment to patient-reported QoL**

Disclosures

Strati: Consultant – *AbbVie-Genmab, ADC Therapeutics, AstraZeneca-Acerta, BeiGene, Incyte Corporation, Ipsen, Kite Pharma/Gilead, Roche-Genentech, Sobi*; Research funds – *ADC Therapeutics, ALX Oncology, AstraZeneca-Acerta, Kite Pharma/Gilead, Sobi*. **Poh:** Advisory board – *Acrotech, AstraZeneca, Ipsen, Seagen*; Research funding – *Astex, Dren Bio, Incyte Corporation, Seagen*. **Trneny:** Honoraria – *AbbVie, Amgen, Bristol Myers Squibb, Gilead Sciences, Incyte Corporation, Janssen, MorphoSys, Roche, Takeda*; Consultant/advisory board – *AbbVie, Amgen, Bristol Myers Squibb, Celgene, Gilead Sciences, Incyte Corporation, Janssen, MorphoSys, Roche, Takeda*; Travel/accommodation/expenses – *AbbVie, Bristol Myers Squibb, Gilead Sciences, Janssen, Roche, Takeda*. **Hübel:** Advisory board/speakers' bureau – *AbbVie, BeiGene, Bristol Myers Squibb, EUSA/Recordati, Gilead Sciences, Incyte Corporation, Novartis, Roche, Servier*. **Luminari:** Advisory board – *AbbVie, Bristol Myers Squibb, Genmab, Incyte Corporation, Janssen, Kite Pharma/Gilead, Novartis, Regeneron, Roche*. **Scholz:** Honoraria – *AstraZeneca, Gilead Sciences, Janssen, Pfizer, Roche*; Advisory board – *Bristol Myers Squibb, Celgene, Daiichi Sankyo, Gilead Sciences, Hexal, Incyte Corporation, Janssen, Merck Serono, Novartis, Roche, Takeda*. **Salar:** Consultant/speakers' bureau – *AbbVie, AstraZeneca, BeiGene, Incyte Corporation, Ipsen, Roche, Sandoz*; Research grant – *Gilead Sciences*. **Paneesha:** Honoraria – *AbbVie, BeiGene, Celgene, Gilead Sciences, Janssen, Roche*. **Wahlin:** Consultant – *Roche*; Research grant – *Gilead Sciences*; Honoraria – *Incyte Corporation, MorphoSys*. **Colucci, Arbushites, Amoloja, Wu:** Employment and stock ownership – *Incyte Corporation*. **Bortolami:** Employment – *IQVIA RDS*; Contractor – *Incyte Corporation*. **Sehn:** Advisory board – *AbbVie, Acerta, Apobiologix, AstraZeneca, Celgene, Debiopharm, Genentech, Genmab, Gilead Sciences, Incyte Corporation, Janssen, Karyopharm Therapeutics, Kite Pharma/Gilead, Lundbeck, Merck, MorphoSys, Novartis, Sandoz, Takeda, TG Therapeutics, Verastem Oncology*; Advisory board/research grants – *Teva*; Advisory board/speakers' bureau – *Roche, Seattle Genetics*.

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