

DOP102

Improvements in patient-reported fatigue among patients with moderately to severely active ulcerative colitis (UC) treated with obefazimod induction therapy: pooled results from the 8-week ABTECT-1 and ABTECT-2 Phase 3, double-blind, placebo-controlled induction trials

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Conflicts of Interest Disclosure

Consulting and advisory board member for:

Abbvie, Abivax, Arena Pharmaceuticals, Astra Zeneca, Boehringer Ingelheim International GmbH, Bristol-Meyer Squibb, Eli Lilly and Company, F. Hoffmann-La Roche Ltd, Genentech Inc, Gilead, Janssen Pharmaceuticals, Merck, Pfizer Inc, Prometheus Biosciences, Takeda Pharmaceuticals.

BACKGROUND

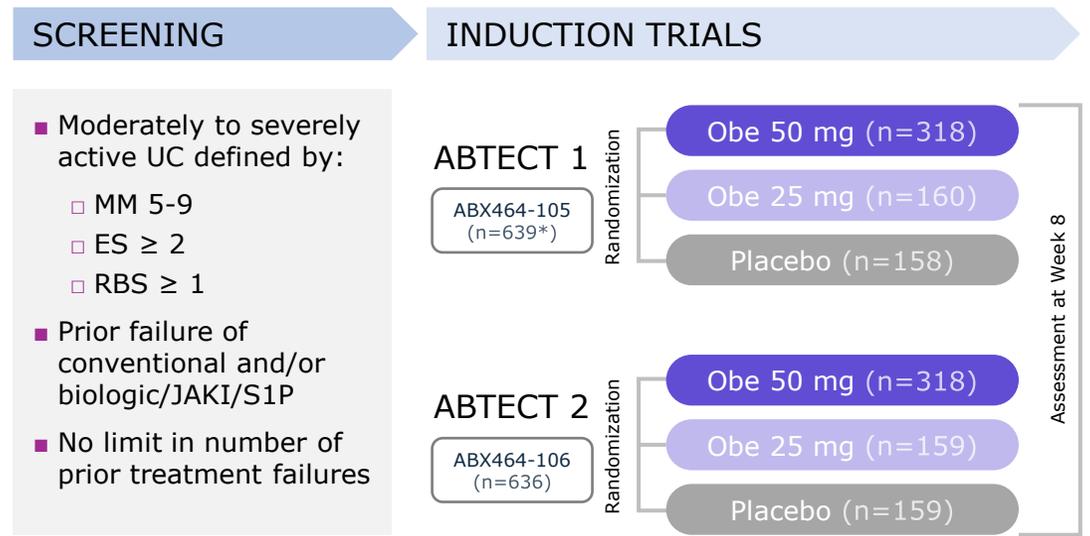
- Obefazimod (Obe) is an oral, once-daily (QD), small molecule that enhances expression of microRNA-124, which restores mucosal immune balance through regulation of Th17 cells and macrophages. Obe has shown efficacy in patients (pts) with moderately to severely active ulcerative colitis (UC).¹⁻³

- Patients (pts) with UC report fatigue as one of the major complaints which negatively impacts quality of life. Here we report efficacy data from two phase 3, 8-week, induction trials on patient-reported fatigue.

METHODS

- In the Phase 3 ABTECT 1 and ABTECT 2 trials, patients were randomized 2:1:1 to receive Obe 50 mg QD, Obe 25 mg QD, or placebo QD (PBO) for 8 weeks.
- Patients reported their fatigue using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) and Fatigue Numerical Rating Scale (NRS).⁴⁻⁶
- FACIT-F was assessed at baseline and week 8. FACIT-F includes 13 items that measure self-reported fatigue and its impacts on daily activities. Scores range from 52 to 0, higher scores indicate less fatigue.
 - Meaningful within patient change is defined as a change of ≥ 5 points. FACIT-F remission > 40 .⁷
- Fatigue NRS was collected in a daily electronic diary and patients rated fatigue on a scale from 0 to 10, higher scores indicate worse fatigue. Fatigue NRS remission ≤ 2 .⁶

Design of ABTECT Induction Trials



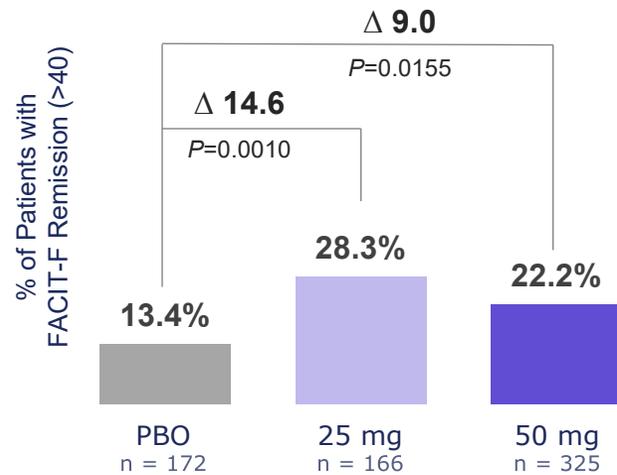
* 3 pts in ABTECT 1 were randomized but not treated

RESULTS

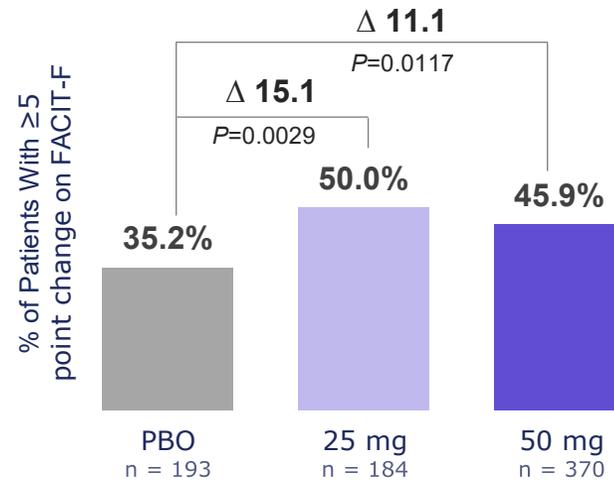
FACIT-F: Obefazimod Treatment Improves Patient-Reported Fatigue

- A total of 1272 patients were randomized and treated in ABTECT-1 (n=636) and ABTECT-2 (n=636). Of these, 747 patients completed the FACIT-F at Baseline, and 1241 patients completed the Fatigue NRS at Baseline and were included in this analysis.

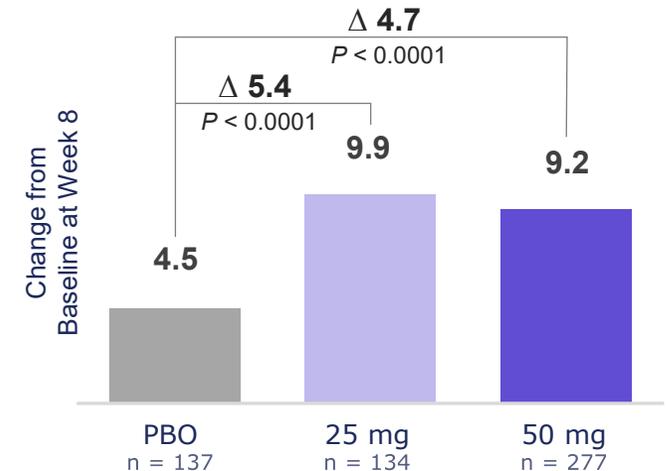
Percent of patients with fatigue remission (>40) as measured by the FACIT-F at Week 8



Percent of patients with clinically meaningful change (≥ 5) on the FACIT-F at Week 8



Mean change in FACIT-F scores (range 0-52) from Baseline to Week 8



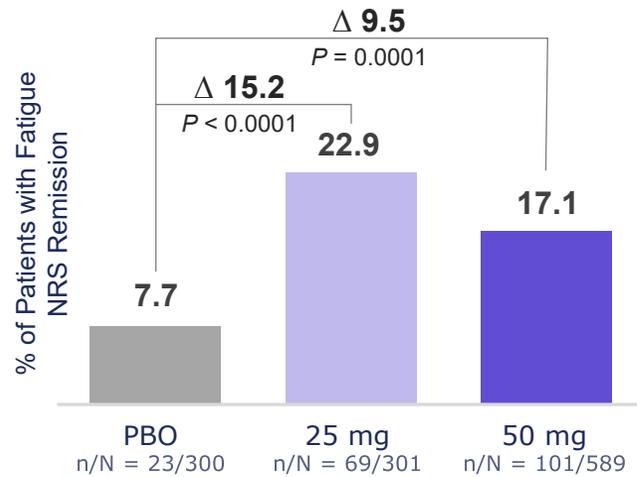


RESULTS (Continued)

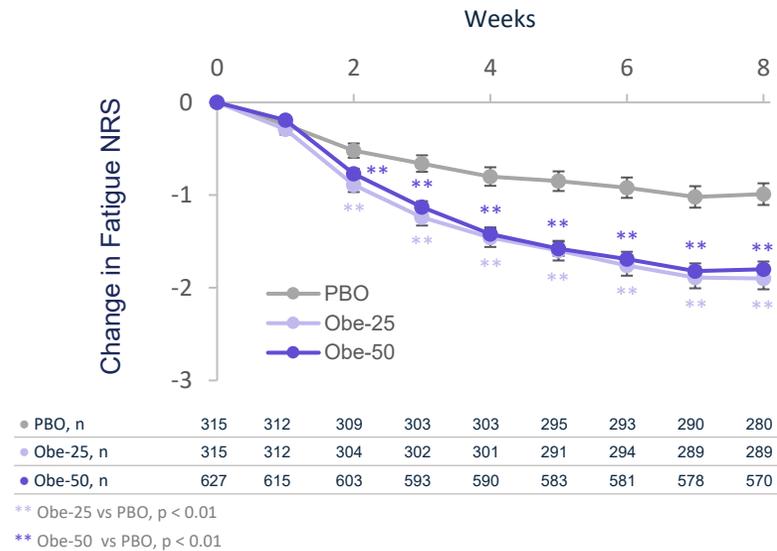
Fatigue NRS: Obefazimod Treatment Improves Patient-Reported Fatigue

- Improvements in fatigue were observed as early as 2 weeks.

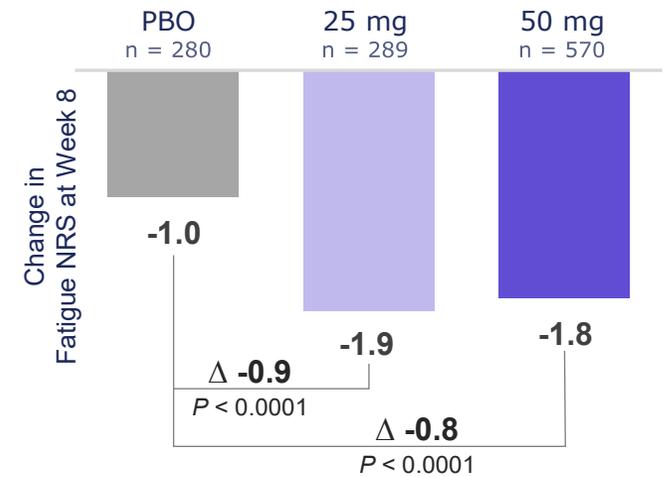
Percent of patients with Fatigue NRS remission (≤ 2) at Week 8



Mean change in Fatigue NRS scores from Baseline to Weeks 1-8



Mean change in Fatigue NRS scores (range 0-10) from Baseline to Week 8



CONCLUSIONS

Patients with moderately to severely active UC treated with obefazimod reported marked improvements in fatigue measured by FACIT-F and the Fatigue NRS across both ABTECT induction trials

Patients reported improvements in fatigue as early as 2 weeks after initiating treatment