

# P0713 Improvements in patient-reported bowel urgency and nocturnal bowel movements 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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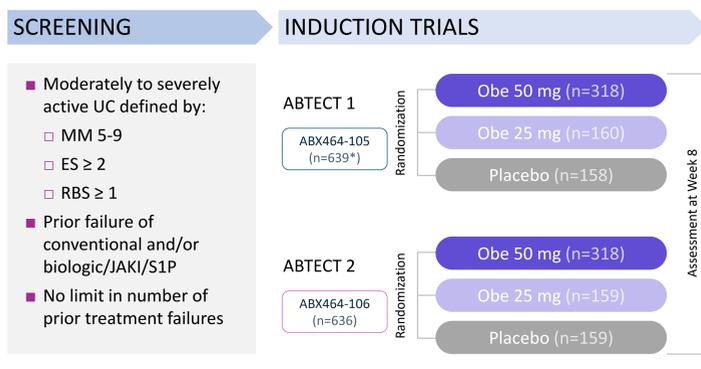
## Background

- 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).<sup>1-3</sup>
- Patients with UC suffer frequent bowel movements accompanied with bowel urgency and nocturnal bowel movements which negatively impact quality of life.<sup>4,5</sup>
- Here we report efficacy data from two Phase 3, 8-week, induction trials on these patient-reported symptoms.

## 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 for 8 weeks (Figure 1).

Figure 1 Design of ABTECT induction trials



\* 3 pts in ABTECT 1 were randomized but not treated

- Patients reported bowel urgency and nocturnal bowel movements using a single-item question [yes/no] in a daily electronic diary.
- Bowel urgency and nocturnal bowel movements scores were based on the total number of days a subject reported bowel urgency or nocturnal bowel movements over the 7 days leading up to the timepoint (scores range 0-7).
- A response was defined as no bowel urgency or nocturnal bowel movements over the closest 3 consecutive days or 4 non-consecutive days in the 7 days closest to the timepoint.<sup>6</sup>

## Statistical Analysis

- Mean changes in bowel urgency and nocturnal bowel movements from Baseline to Week 8 were reported descriptively by week.
- The proportions of patients with no bowel urgency and nocturnal bowel movements at Week 8 were determined.
- Patients that received at least one dose and had baseline bowel urgency >0 and nocturnal bowel movements >0 were included in the analysis of proportions. All p-values are nominal.

## References

- Vermeire S et al. *J Crohns Colitis*. 17: 1689-97, 2023.
- Vermeire S et al. *Gastroenterology*. 160: 2595-98, 2021.
- Vermeire S et al. *The Lancet Gastroenterology & Hepatology*. 7: 1024-35, 2022.
- Dulai PS et al. *Aliment Pharmacol Ther*. 51 (11), 2047-66, 2020.
- Newton L et al. *J Patient Rep Outcomes*. 3(1):66, 2019.
- Danese S et al. *Inflamm Bowel Dis*. 29(11): 1723-9, 2023.

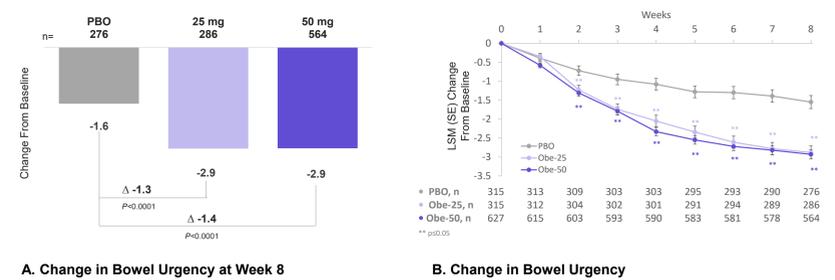
## Disclosures

MD (consultant or speaker's fees) 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; SD (consultant or speaker's fees): AbbVie, Ferring, Hospira, Johnson & Johnson, Merck, MSD, Takeda, Mundipharma, Pfizer Inc, Tigenix, UCB Pharma, Vifor, Biogen, Celgene, Allergan, Celtrion, Sandoz, Boehringer Ingelheim; DR (consultant or speaker's fees) Abbvie, Abivax SA, Altrubio, Athos Therapeutics, Inc, Bristol-Myers Squibb, Celtrion, Connect BioPharma, Eli Lilly & Co., Genentech Inc., Iterative Health, Janssen Pharmaceuticals, J&J, Merck & Co., Odyssey Therapeutics, Pfizer, Sanofi, Spyre, Takeda Pharmaceuticals, Vedanta Biosciences, Ventyx (Grant) Takeda; MS (grants, consultant or speaker's fees) Gilead, Celtrion, Janssen, Abbvie, Ferring, Takeda, Pfizer, Eli Lilly, Dr. Falk Pharma, Celgene, MSD, Emerge Health, BMS, Alimentiv; TL (consultant or speaker's fees) Abbvie, Amgen, Janssen Pharmaceuticals, Pfizer, Takeda; FM (consultant or speaker's fees) AbbVie, Amgen, Biogen, Celgene, Celtrion, Dr Falk Pharma, Ferring Pharmaceuticals, Hospira, Janssen, Laboratórios Vitória, MSD, Pfizer, Sandoz, Takeda, UCB, Vifor (Grants) GEDII, National Science Foundation; SN (consultant or speaker's fees) Abbvie, Alfasigma, Amgen, Celtrion, Ferring, Fresenius-Kabi, J&J, Lilly, Medac, MSD, Pfizer, Sandoz, Takeda; CD (consultant) Abivax, Genentech, Regenxbio, PharmacoEvidence, Mucure; AA (consultant or speaker's fees) Abivax, Alfa Sigma, Astra Zeneca, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Celtrion, Eli-Lilly, Entera, Ferring, Galapagos, Gilead, Giuliani, Janssen, Lionhealth, MSD, Nestlé, Pfizer, Protagonist Therapeutics, Roche, Samsung Bioepis, Sanofi, Sandoz, Takeda, Teva Pharmaceuticals, Tillots Pharma, AG Pharma, Novartis; (Grant) Biogen, MSD, Takeda, and Pfizer.

## Results

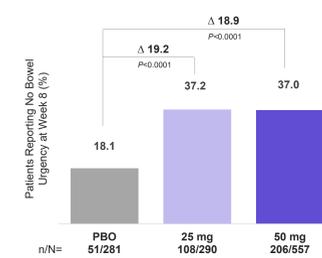
- Patients treated with Obe reported greater improvements in bowel urgency compared to placebo at Week 8 (Figure 2A).
- Improvement in bowel urgency was seen as early as Week 2 (Figure 2B).

Figure 2 Change From Baseline in Bowel Urgency (Days per Week)



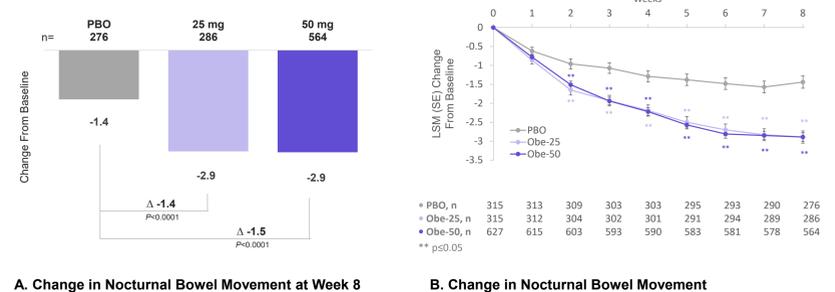
- A greater percentage of patients treated with Obe reported no bowel urgency at Week 8 compared to placebo (Figure 3).

Figure 3 Proportion of Patients Reporting No Bowel Urgency at Week 8 Among Those With Bowel Urgency at Baseline



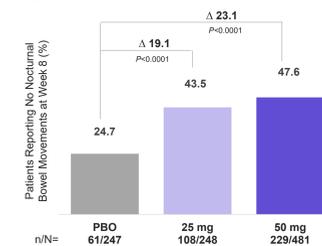
- Patients treated with Obe reported greater improvements in nocturnal bowel movements compared to placebo at Week 8 (Figure 4A).
- Improvement in nocturnal bowel movements was seen as early as Week 2 (Figure 4B).

Figure 4 Change From Baseline in Nocturnal Bowel Movement (Nights per Week)



- A greater percentage of patients treated with Obe reported no nocturnal bowel movements compared to placebo at Week 8 (Figure 5).

Figure 5 Proportion of Patients Reporting No Nocturnal Bowel Movement at Week 8 Among Those With Nocturnal Bowel Movement at Baseline



## Conclusions

Treatment with obefazimod markedly improved bowel urgency and nocturnal bowel movements in patients with moderately to severely active UC across both ABTECT induction trials, with improvements reported as early as 2 weeks.

At Week 8, the proportions of patients treated with obefazimod who reported no bowel urgency or no nocturnal bowel movements were approximately twice those of patients treated with placebo.