

Symptoms of bowel urgency and nocturnal bowel movements are linked with improvement in clinical outcomes among patients with moderately to severely active ulcerative colitis treated with obefazimod: pooled results from the 8-week ABTECT Phase 3 induction trials

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Introduction

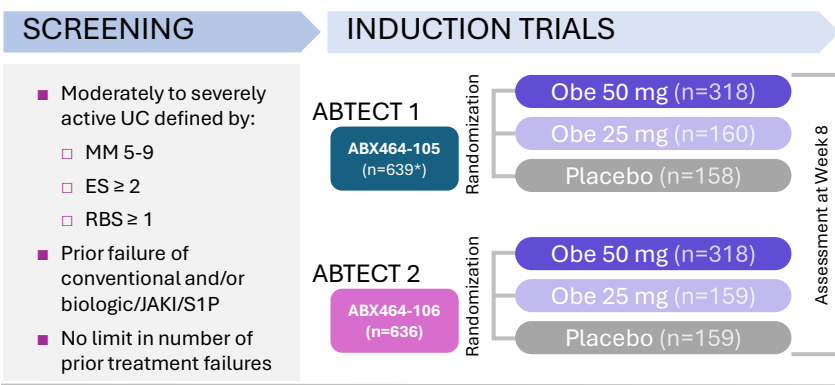
- > Obefazimod (Obe) is an oral, once-daily (QD), small molecule that enhances expression of microRNA-124, an endogenous regulator of inflammation, which restores mucosal immune balance through regulation of Th17 cells and macrophages
- > Obe has shown efficacy in people with moderately to severely active ulcerative colitis (UC) [1-3]
- > People with UC experience frequent bowel movements accompanied by bowel urgency (BU) and nocturnal bowel movements (NBM) which negatively impact quality-of-life (QoL) [4,5]
- > **Here the relationship between histologic and endoscopic mucosal improvement endpoints and BU/NBM frequency in the pooled ABTECT trials is reported**

Methods

Study Design

- > 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 (**Fig 1**)
- > Patients reported BU and NBM using a single-item question [yes/no] in a daily electronic diary
- > BU and NBM scores were based on the total number of days a patient had BU or NBM over the 7 days leading up to the timepoint (scores range 0-7)
- > Endoscopic improvement (EI) was defined as Mayo endoscopic score (MES) of 0 or 1. Endoscopic remission (ER) is defined as MES=0
- > Histologic-endoscopic mucosal improvement (HEMI) is a composite score comprised of Mayo endoscopic subscore (MES) of 0 or 1 and histologic improvement (Geboes Score ≤ 3.1)
- > Histologic-endoscopic mucosal remission (HEMR) is defined as MES=0 and histologic remission (Geboes Score <2.0)

Figure 1. Design of ABTECT Induction Trials



Statistical Analysis

- > Patients who received at least one dose of study treatment and had baseline BU>0 and NBM>0 were included in the analyses of proportions (percentages)
- > BU and NBM frequency were examined by various endoscopic and/or histologic outcomes (Yes/No) at Week 8 for all treatment groups combined
- > All p-values are nominal

Results

- > A total of 1272 patients were randomized and treated in ABTECT-1 (n=636) and ABTECT-2 (n=636): 1128 patients had BU and 976 patients had NBM at Baseline
- > Obe markedly improved clinical histologic and endoscopic outcomes and BU and NBM in patients with moderately to severely active UC across both ABTECT induction trials [6,7]
- > A greater percentage of patients treated with Obe achieved endoscopic improvement or endoscopic remission compared to placebo at Week 8 (**Fig 2**) and HEMI or HEMI without HEMR compared to placebo at Week 8 (**Fig 3**)

Figure 2. Percentage of Patients who Achieved Endoscopic Improvement and Endoscopic Remission at Week 8 of ABTECT Induction Trials

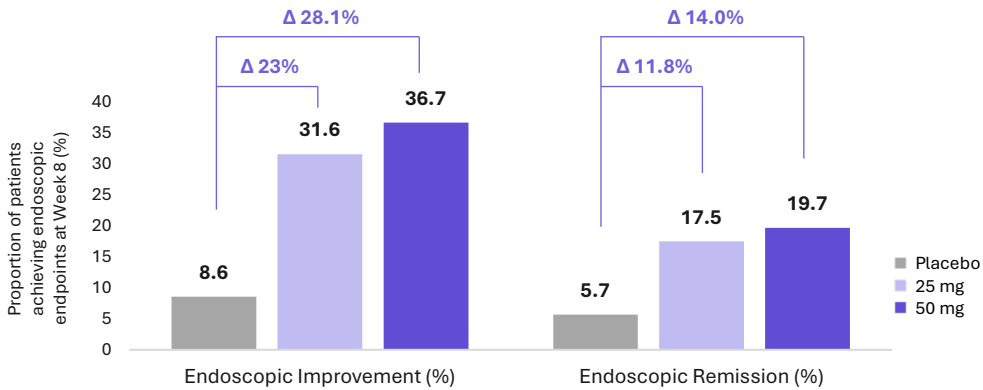
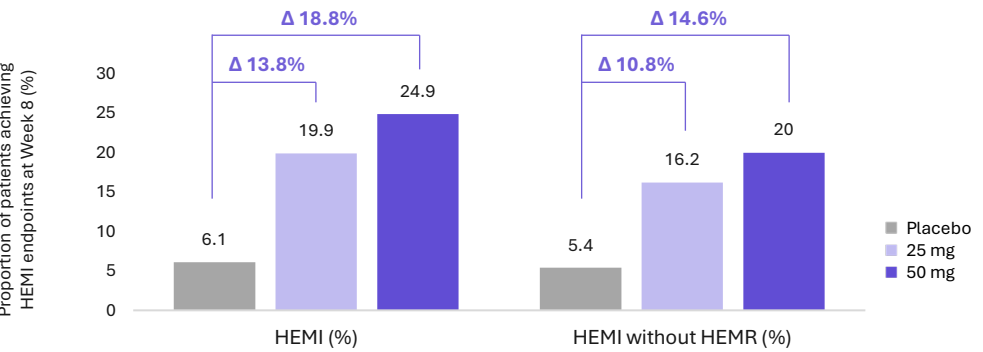
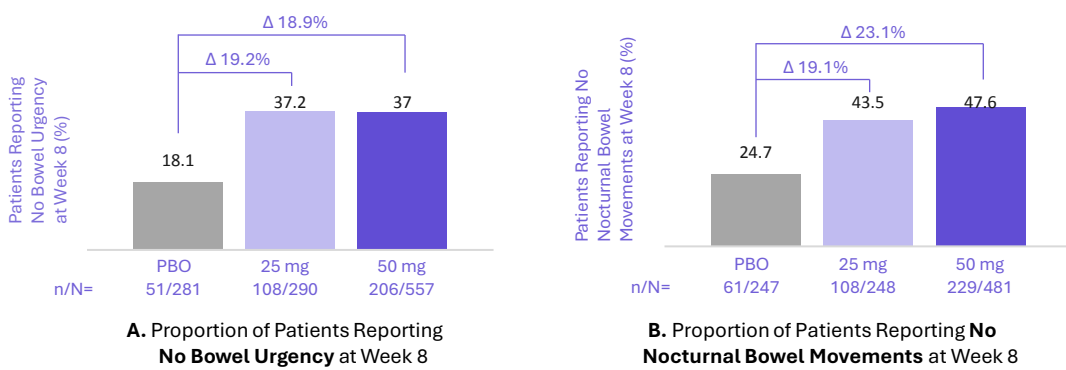


Figure 3. Percentage of Patients who Achieved HEMI and HEMI without HEMR at Week 8 of ABTECT Induction Trials



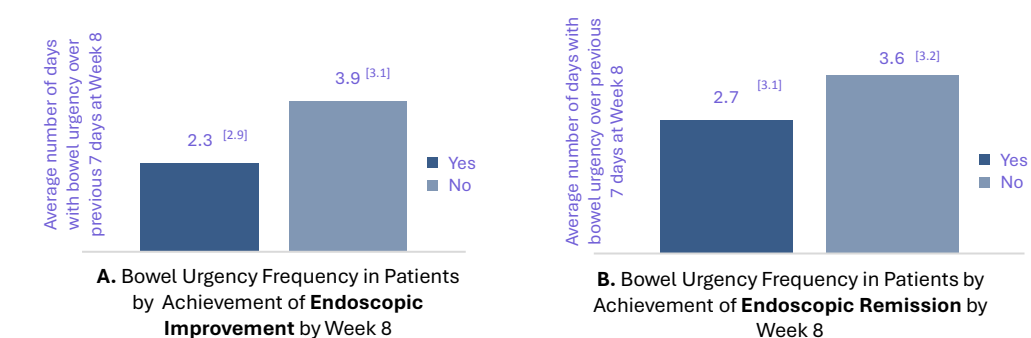
- > A greater percentage of patients treated with Obe reported no bowel urgency and no nocturnal bowel movements compared to placebo at Week 8 (**Figures 4A and 4B**)

Figure 4. Percentage of Patients Reporting No Bowel Urgency and No Nocturnal Bowel Movements at Week 8 of ABTECT Induction Trials



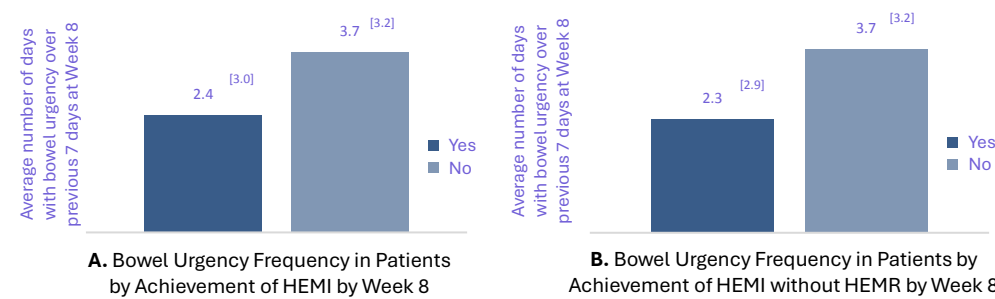
- > Patients who achieved endoscopic improvement or endoscopic remission at Week 8 had on average fewer days of bowel urgency compared to patients not achieving these endoscopic improvements (**Figures 5A and 5B**)

Figure 5. Number of Days of Bowel Urgency among Patients who Achieved Endoscopic Improvement and Endoscopic Remission at Week 8



- > Patients who achieved HEMI or HEMI without HEMR at Week 8 had on average fewer days of bowel urgency compared to patients not achieving these histologic and endoscopic improvements (**Figures 6A and 6B**)

Figure 6. Number of Days of Bowel Urgency among Patients who Achieved HEMI or HEMI without HEMR at Week 8

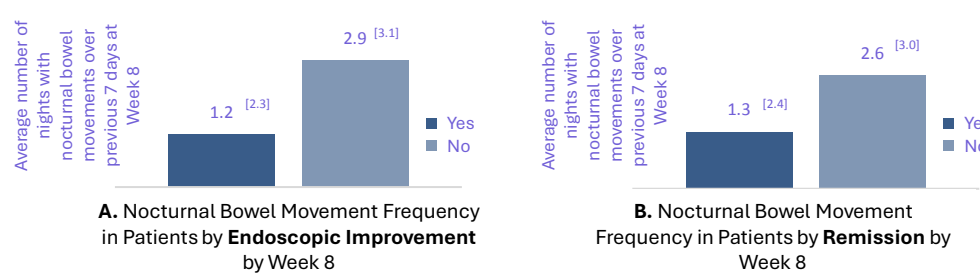


Author's Conclusions

- > **In the ABTECT trials, patients who achieved endoscopic and histologic mucosal outcomes of improvement or remission at Week 8 experienced on average fewer days of bowel urgency and fewer nights of nocturnal bowel movements than patients who did not achieve these outcomes**
- > These findings support the positive impact of achieving these endoscopic and histologic mucosal outcomes on patient-reported QoL

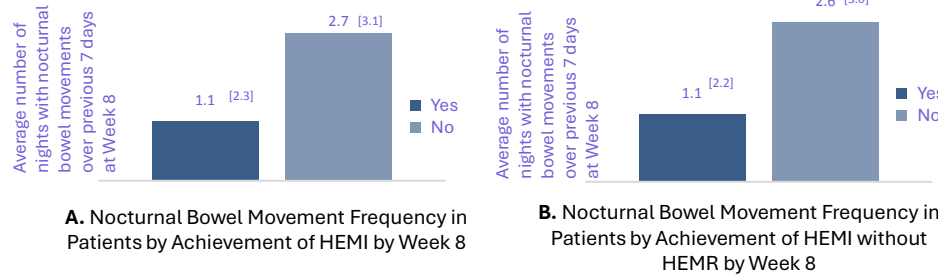
- > Patients who achieved endoscopic improvement or endoscopic remission at Week 8 had on average fewer nights of nocturnal bowel movements compared to patients not achieving these endoscopic improvements (**Figures 7A and 7B**)

Figure 7. Number of Nights of Nocturnal Bowel Movements among Patients who Achieved Endoscopic Improvement and Endoscopic Remission at Week 8



- > Patients who achieved HEMI or HEMI without HEMR at Week 8 had on average fewer nights of bowel urgency compared to patients not achieving these endoscopic improvements (**Figures 8A and 8B**)

Figure 8. Number of Nights of Nocturnal Bowel Movements among Patients who Achieved HEMI or HEMI without HEMR at Week 8



References

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Disclosures

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