P0928 Improvements in patient-reported work productivity and activity impairment 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

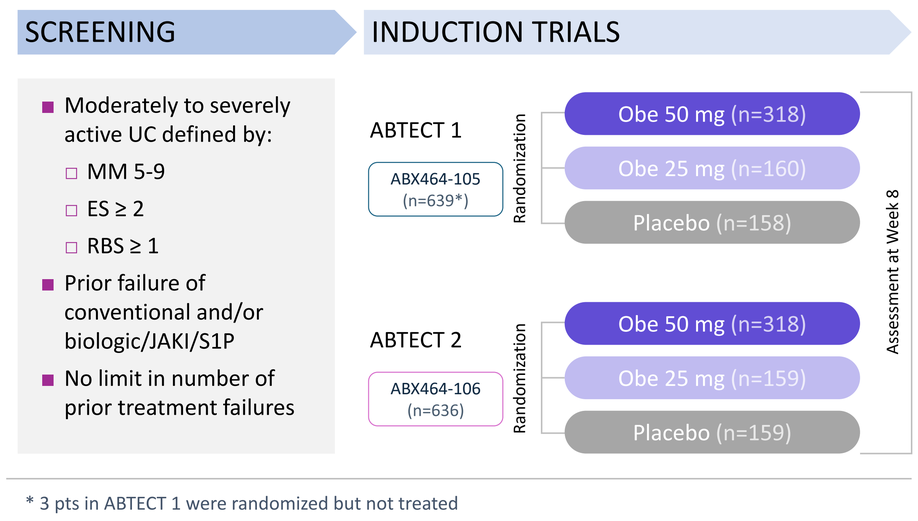
- Obefazimod (Obe) is an oral, once-daily (QD), small molecule that enhances expression of microRNA-124, which restores mucosal immune balance through regulation of Th17 cells and macrophages. Obe has shown efficacy in patients (pts) with moderately to severely active ulcerative colitis (UC).[1-3]
- Patients with UC experience symptoms which negatively impact their ability to work.[4]
- Here we report the impact of 8-week Obe treatment on the patient-reported Work Productivity and Activity Impairment Questionnaire for adults with UC (WPAI:UC) in patients enrolled in the ABTECT trials.

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 (**Figure 1**).

Figure 1 Design of ABTECT induction trials



* 3 pts in ABTECT 1 were randomized but not treated

- Patients' work productivity was assessed using the WPAI:UC, which measures impairments in paid and unpaid work using 6 questions across 4 domains:[5]
  - absenteeism (work missed)
  - presenteeism (work impairment or reduced effectiveness at work)
  - activity impairment (activities not including paid work, for example cleaning or shopping)
  - overall work impairment (reflects both absenteeism and presenteeism)
- Scores were reported as impairment percentages; higher numbers signifying more impairment and less productivity.
- A clinically meaningful change threshold was defined as an absolute decrease of the following for each domain: [6,7]
  - ≥7.3% in overall work impairment
  - ≥6.5% in absenteeism
  - ≥6.1% in presenteeism
  - ≥8.5% in activity impairment

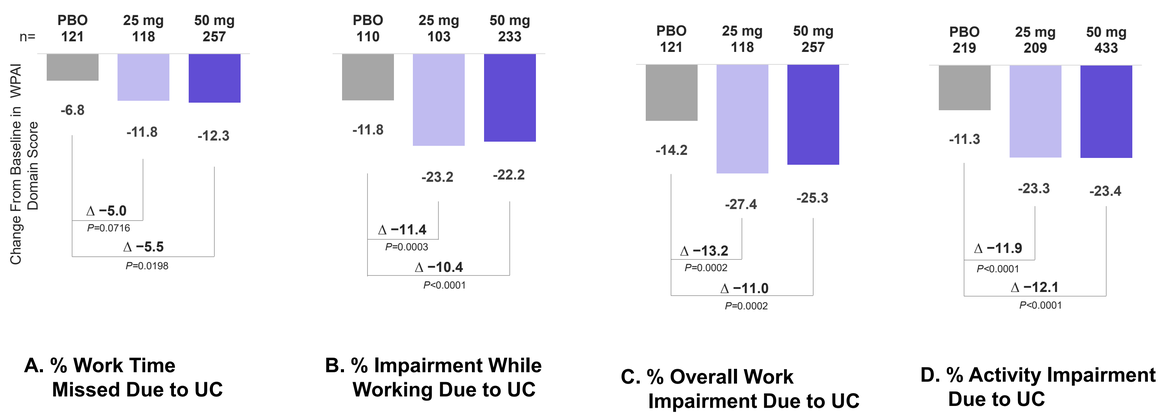
Statistical Analysis

- Mean changes in the WPAI domains from Baseline to Week 8 were reported descriptively.
- The proportion of patients with a clinically meaningful change on each WPAI domain at Week 8 was determined. All p-values are nominal.

Results

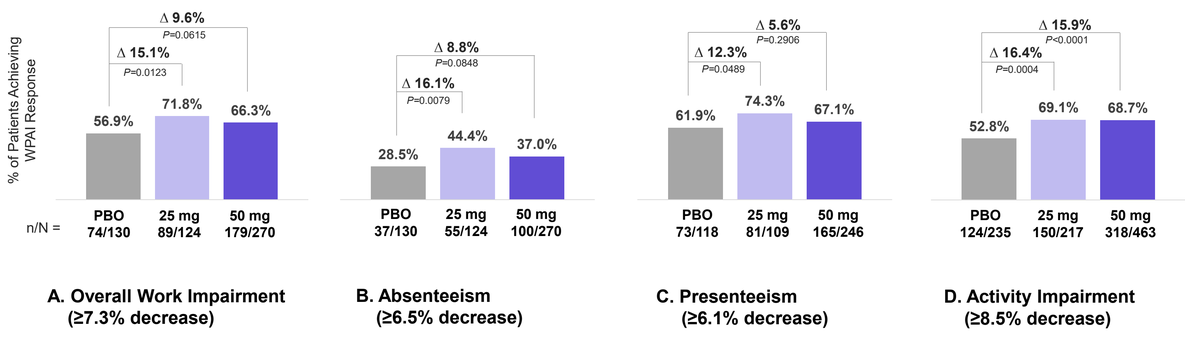
- Patients treated with Obe reported decreased absenteeism, presenteeism, overall work impairment, and activity impairment compared to placebo at Week 8 (with most domains reaching statistical significance) (**Figure 2**).

Figure 2 Change from Baseline to Week 8 in WPAI:UC domain scores



- A greater proportion of patients treated with Obe reported a clinically meaningful change on activity impairment at Week 8 compared to placebo, reaching statistical significance for both Obe doses (**Figure 3**).
- Nominally greater proportions of Obe-treated patients also achieved a clinically meaningful change for the overall work impairment, presenteeism and absenteeism domains at Week 8 compared to placebo (**Figure 3**).

Figure 3 Proportion of Patients With Clinically Meaningful Change on WPAI Domains at Week 8



Conclusions

Patients with moderately to severely active UC treated with Obefazimod experienced markedly improved productivity at work, reduced absenteeism, reduced impairment in work activities, and reduced impairment in activities of daily living across both ABTECT induction trials.

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Disclosures

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