DOP061

Improvements in patient-reported, disease-specific and overall quality-of-life 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/or speaking fees from:

AbbVie, Amgen, Arena Pharmaceuticals, Celgene, Celltrion Ferring, Fresenius Kabi, Galapagos, Janssen, J&J, Merck Sharp & Dohme, Pfizer Inc, Sandoz, Takeda.

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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]

- Here we report efficacy data from two Phase 3, 8-week, induction trials on patient-reported, disease-specific and overall quality-of-life (QoL).

METHODS

- In both ABTECT 1 and ABTECT 2, patients completed a disease-specific QoL measure and an overall QoL measure at Baseline and Week 8.

The Inflammatory Bowel Disease Questionnaire[4]

- The IBDQ is a disease-specific QoL questionnaire consisting of 32 items across 4 domains (Emotional functioning, Bowel symptoms, Social functioning, Systemic symptoms).
- Clinically meaningful change on the IBDQ is defined as ≥16 points.[5]
- IBDQ remission is defined as an IBDQ total score of ≥170.2.

The EQ-5D-5L

- The EQ-5D-5L measures overall QoL and consists of an Index Score and a Visual Analog Scale.[6]
- EQ-5D-5L Index Score ranges from 0-1. Scores on the EQ-5D-5L Visual Analog Scale range from 0-100.
- Clinically meaningful change was defined as ≥0.076 points on the EQ-5D-5L Index and ≥10.9 on the Visual Analog Scale.[7]
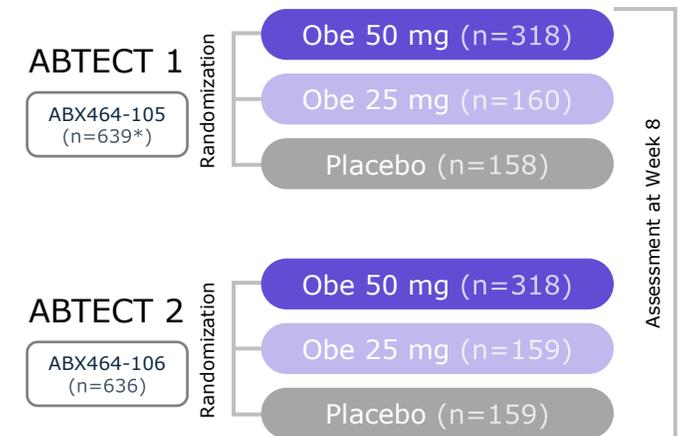
Statistical Analysis

- Patients that received at least one dose and had baseline IBDQ data or EQ-5D-5L data were included in these analyses. Data were analyzed as observed. All p-values are nominal.

Design of ABTECT Induction Trials

SCREENING	INDUCTION TRIALS

- Moderately to severely active UC defined by:
  - MM 5-9
  - ES ≥ 2
  - RBS ≥ 1
- Prior failure of conventional and/or biologic/JAKI/S1P
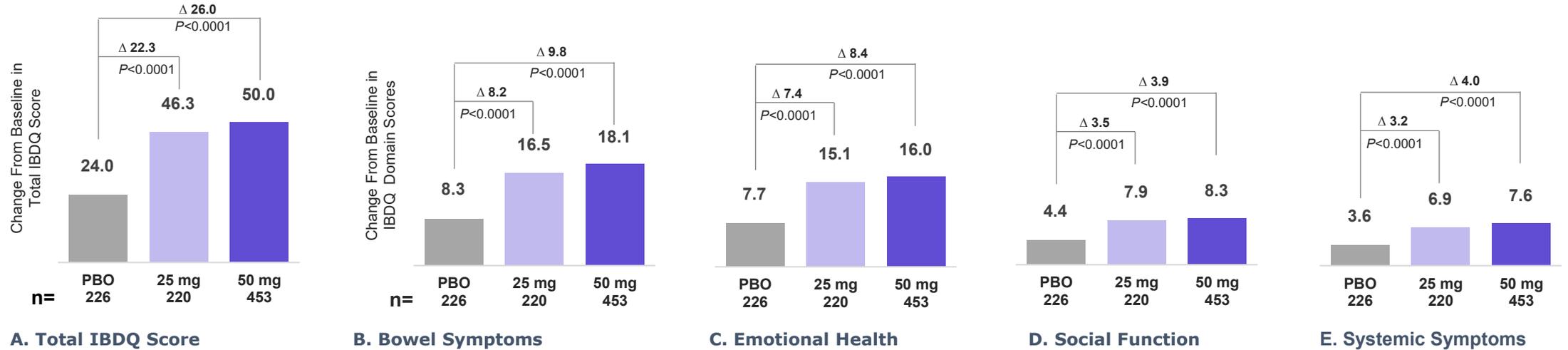- No limit in number of prior treatment failures

ABTECT 1
ABX464-105 (n=639*)
- Obe 50 mg (n=318)
- Obe 25 mg (n=160)
- Placebo (n=158)

Randomization

ABTECT 2
ABX464-106 (n=636)
- Obe 50 mg (n=318)
- Obe 25 mg (n=159)
- Placebo (n=159)

Randomization

Assessment at Week 8

* 3 pts in ABTECT 1 were randomized but not treated
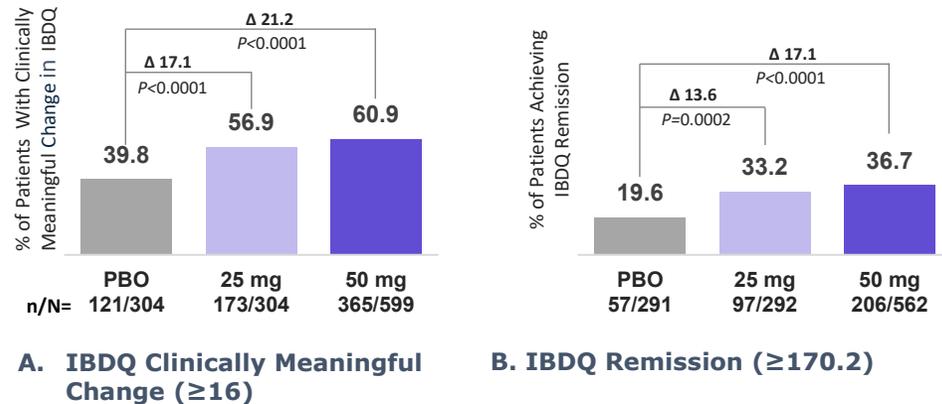
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Obefazimod Treatment Improves Disease-Specific Patient-Reported QoL

Change in IBDQ Total and Domain Scores from Baseline to Week 8

A. Total IBDQ Score

B. Bowel Symptoms

C. Emotional Health

D. Social Function

E. Systemic Symptoms

Percent of Patients with Clinically Meaningful Change and IBDQ Remission at Week 8

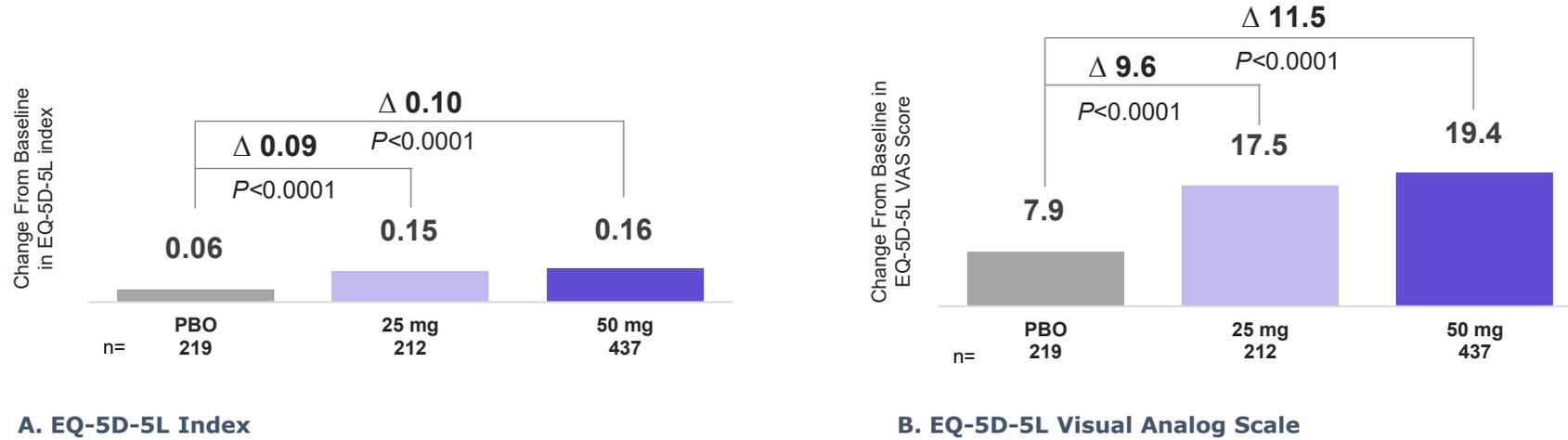**A. IBDQ Clinically Meaningful Change (≥16)**

B. IBDQ Remission (≥170.2)

A total of 1272 patients were randomized and treated in ABTECT-1 (n=636) and ABTECT-2 (n=636). Of these,1207 had IBDQ, 1137 had EQ-5D-5L Index and 1,180 had EQ-5D-5L VAS data at Baseline.
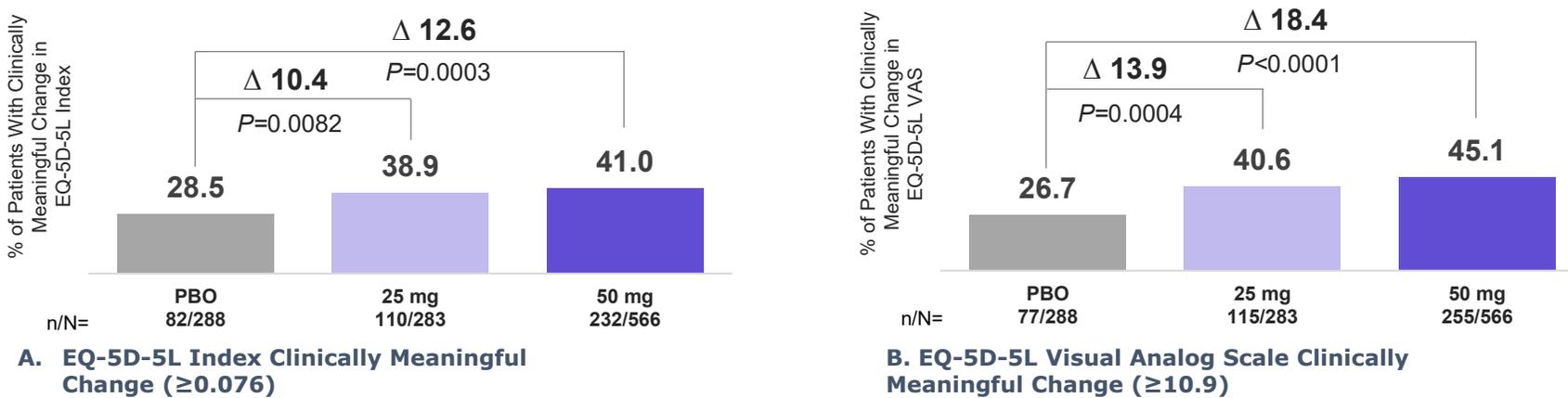
Obefazimod Treatment Improves Overall Patient-Reported QoL measured by the EQ-5D-5L Index Score and the EQ-5D-5L Visual Analog Scale

Change in EQ-5D-5L Index and Visual Analog Scale Scores from Baseline to Week 8

A. EQ-5D-5L Index

B. EQ-5D-5L Visual Analog Scale

Patients with Meaningful Change on EQ-5D-5L Index and Visual Analog Scale from Baseline to Week 8

A. EQ-5D-5L Index Clinically Meaningful Change (≥0.076)

B. EQ-5D-5L Visual Analog Scale Clinically Meaningful Change (≥10.9)

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Patients treated with obefazimod reported improvement in both disease-specific and general quality-of-life across both treatment doses in the ABTECT induction trials

Improvements in both measures of patient-reported quality-of-life were observed 8 weeks after initiation of treatment

These improvements are consistent with other clinical measures of treatment effect in these trials