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INTRODUCTION

- 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 (NCT05507203, NCT05507216) on patient-reported, disease-specific and overall quality-of-life (QoL).

METHOD

- In both ABTECT trials (Figure 1), pts completed a disease-specific QoL measure and an overall QoL measure at Baseline and Week 8.

The Inflammatory Bowel Disease Questionnaire⁴

- 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 .

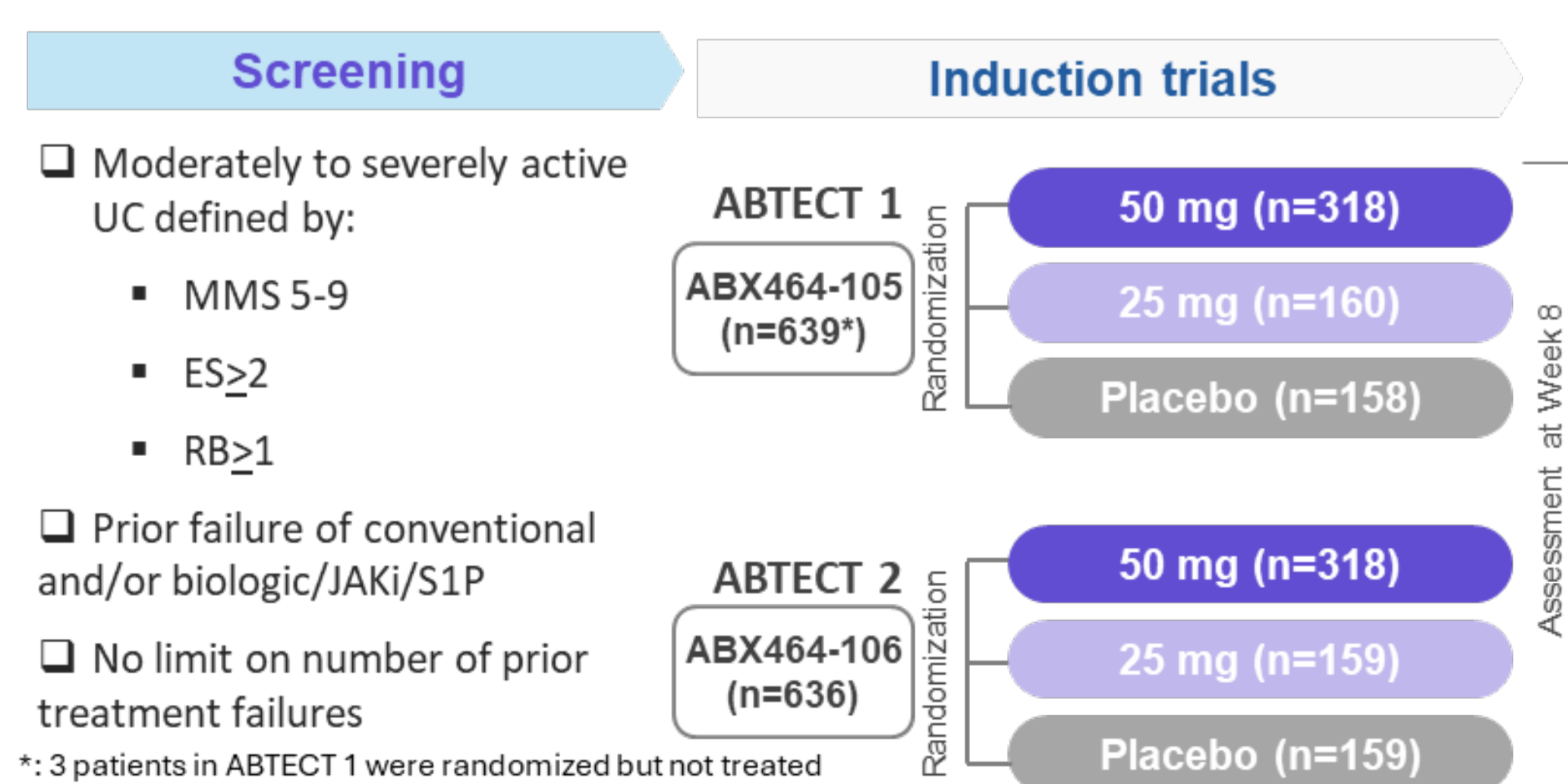
The EQ-5D-5L

- 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 is defined as ≥ 0.076 points on the EQ-5D-5L Index and ≥ 10.9 on the Visual Analog Scale.⁷

Statistical Analysis

- Pts 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.

Fig. 1: Design of ABTECT induction trials



RESULTS

A total of 1272 pts 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 1180 had EQ-5D-5L VAS data at Baseline.

Obefazimod Treatment Improves Disease-Specific Patient-Reported QoL

- Pts treated with Obe reported higher mean IBDQ scores compared to placebo at Week 8 (Figure 2).
- A greater proportion of pts treated with Obe reported a clinically meaningful improvement at Week 8 compared to placebo (Figure 3A).
- A greater proportion of pts treated with Obe achieved IBDQ remission at Week 8 compared to placebo (Figure 3B).

Fig. 2: Change in IBDQ Total and Domain Scores from Baseline to Week 8

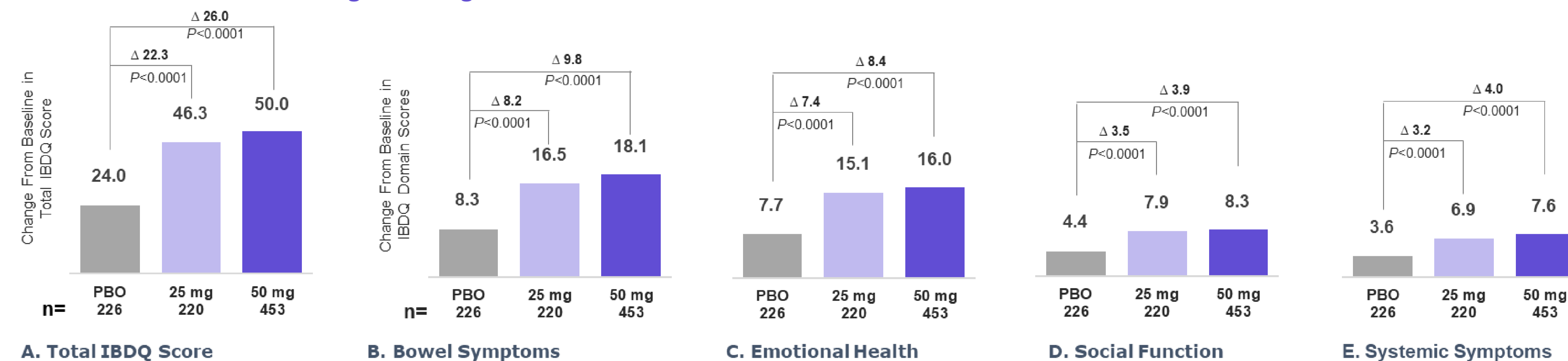
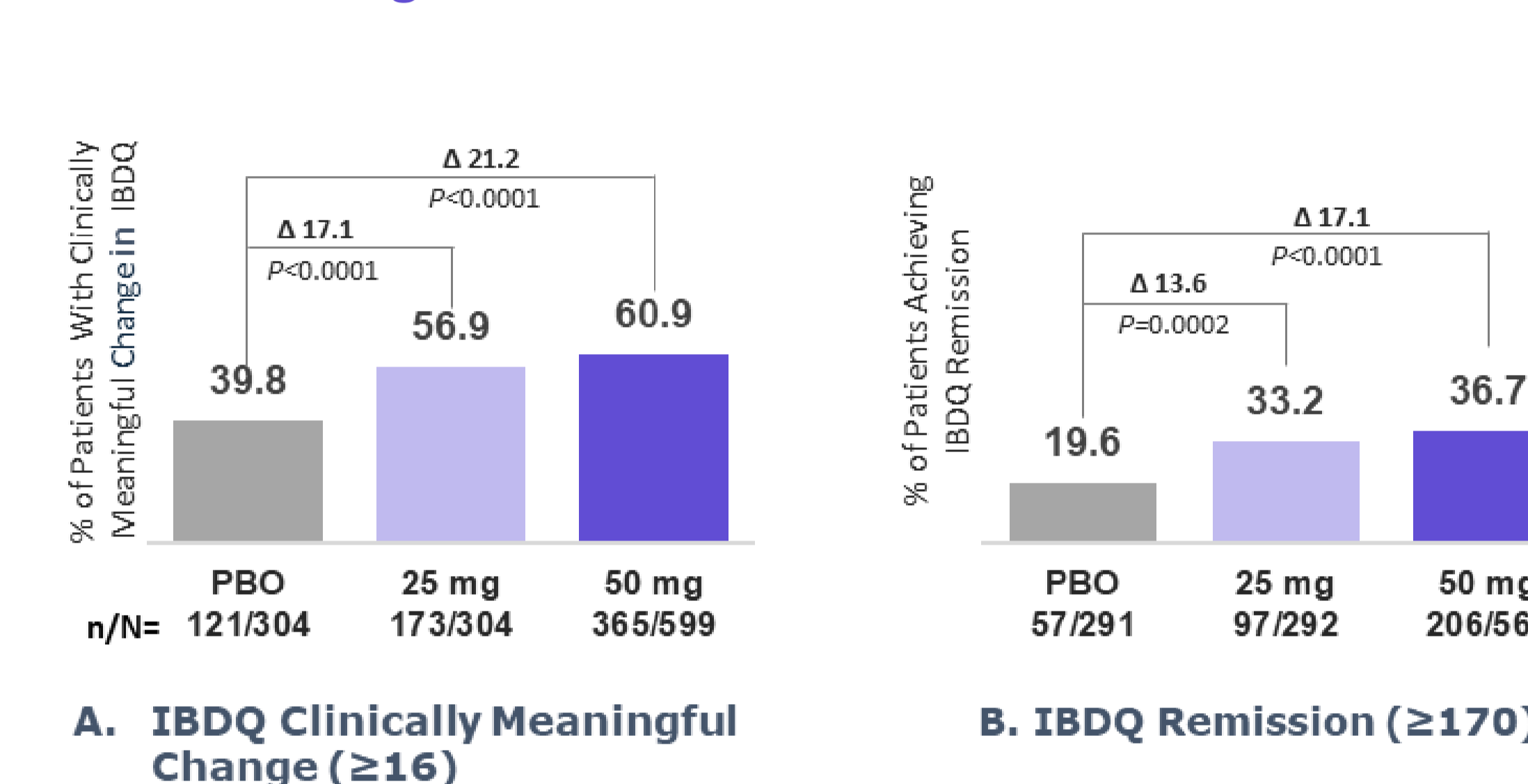


Fig. 3: Percent of Patients with Clinically Meaningful Change and IBDQ Remission at Week 8



Obefazimod Treatment Improves Overall Patient-Reported QoL measured by the EQ-5D-5L Index Score and the EQ-5D-5L Visual Analog Scale

- Patients treated with Obe reported higher EQ-5D-5L Index and VAS scores at Week 8 compared to placebo (Figure 4).
- A greater proportion of patients treated with Obe had a meaningful improvement on the EQ-5D-5L Index and VAS compared to placebo at Week 8 (Figure 5).

Fig. 4: Change in EQ-5D-5L Index and Visual Analog Scale Scores from Baseline to Week 8

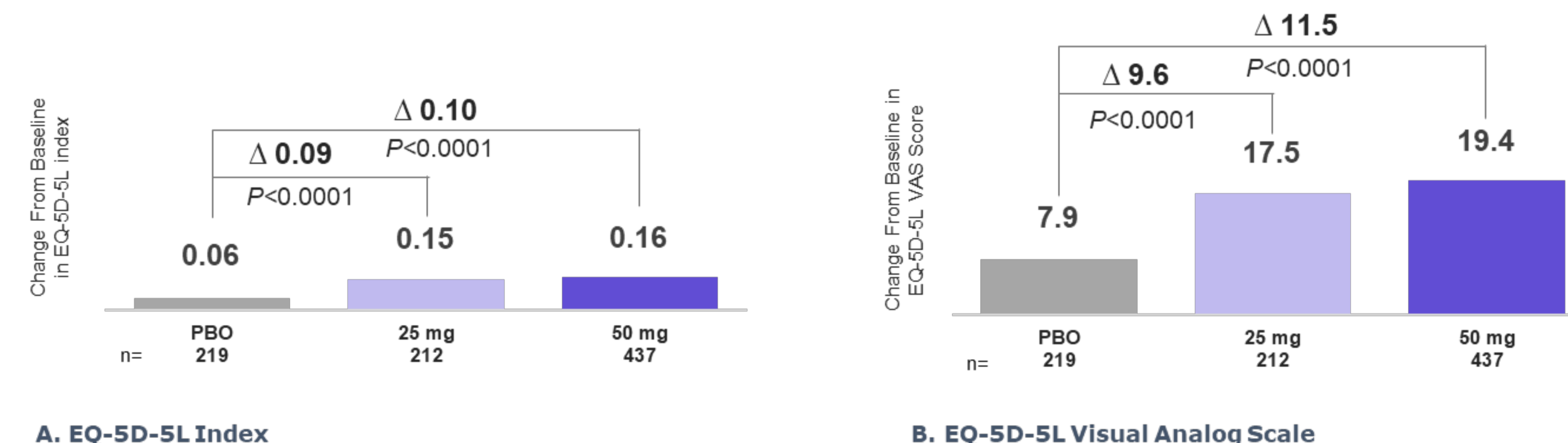
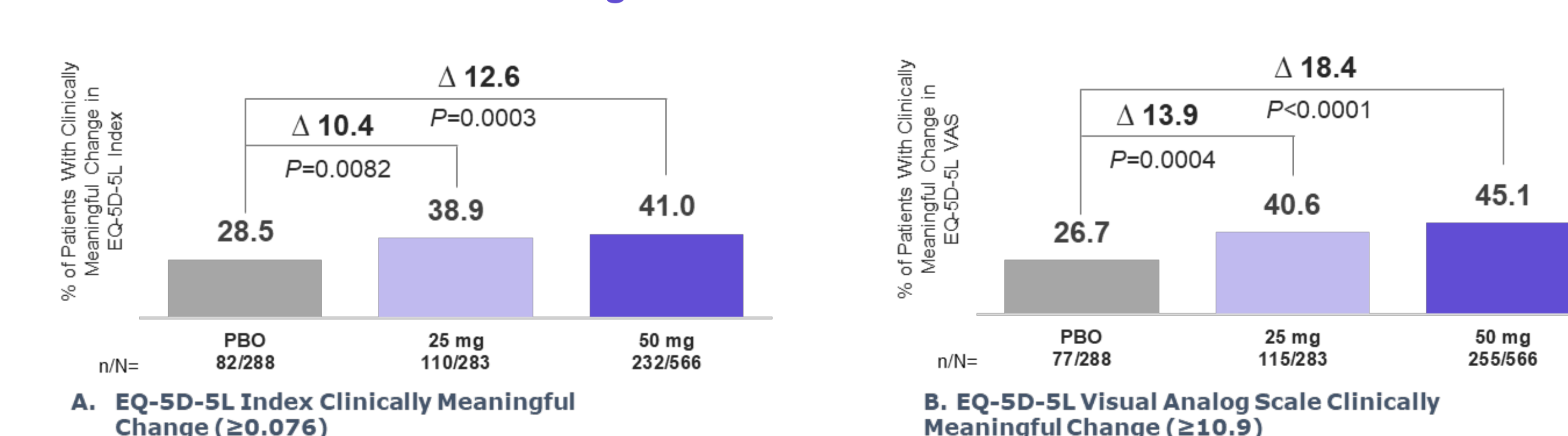


Fig. 5: Patients with Meaningful Change on EQ-5D-5L Index and Visual Analog Scale from Baseline to Week 8



CONCLUSIONS

- Patients treated with obefazimod reported improvement in both disease-specific and general quality-of-life across both treatment doses in the ABTECT induction trials
- These improvements are consistent with other clinical measures of treatment effect in these trials

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DISCLOSURES

†E5 (consultant/speaker's fees) AbbVie, Abivax, Adiso Therapeutics, AgomAb, Alimentiv, Amgen, Arena Pharmaceuticals, Artizan Biosciences, Artigen Therapeutics, AstraZeneca, Bacainn Therapeutics, Biora Therapeutics, Boehringer Ingelheim, Boston Pharmaceuticals, Bristol Myers Squibb, Calibr, Celltrion, ClostraBio, Connect Biopharm, Cytokil Pharma, Eli Lilly and Company, Entera, Evomune, Ferring, Fresenius Kabi, Galapagos, Gilead Sciences, Genentech, Glaxo SmithKline, Gossamer Bio, HMP Acquisition, Imhotec, Immunic, InDex Pharmaceuticals, Innovation Pharmaceuticals, Inotrem, Ironwood Pharmaceuticals, Janssen, Johnson & Johnson, Kaleido, Kalypso, Merck, Mirabilis, Morphic Therapeutic, MRM Health, OSE Immunotherapeutics, Pfizer, Progenity, Prometheus Biosciences, Prometheus Laboratories, Protagonist Therapeutics, C32 Bio, Redhill Biopharma, Sun Pharma Global, Surroze, Synlogic Operating Company, Takeda, Target RWE, Theravance Biopharma R&D, TLL Pharmaceutical, USWM Enterprises, Ventix Biosciences, Viala Bio, and stock options from Ventix Biosciences; US (consultant or speaker's fees) AbbVie, Abivax, Amgen, Galapagos, Janssen, Eli Lilly, Janssen; (Grant) AbbVie, Abivax, Boehringer Ingelheim, BMS, Celgene, Eli Lilly, Gilead Sciences, Galapagos, Janssen, Pfizer, Roche, and Takeda Pharmaceuticals; RA (consultant or speaker's fees) AbbVie, Abivax, AstraZeneca, BMS, Celltrion Healthcare, Galapagos, J&J, Lilly, MSD, Pfizer, and Takeda Pharma; FI (consultant or speaker's fees) AbbVie, Amgen, Arena Pharmaceuticals, Celgene, Celltrion Ferring, Fresenius Kabi, Galapagos, Janssen, J&J, Merck Sharp & Dohme, Pfizer Inc, Sandoz, Takeda, (Grant) AbbVie, Amgen, Eurogenerics, J&J, and Takeda; PI (consultant or speaker's fees) Abivax, Eli Lilly, Roche, AbbVie, Morphic Therapeutic, Janssen, Microbiotica, Optimapharm, Genentech, Bristol Myers Squibb, Cinclus Pharma, Boehringer Ingelheim, Pfizer; *† (consultant or speaker's fees) AbbVie, Celltrion, MSD, J&J, Takeda, Amgen, Alphasigma, Lilly, Thabior Therapeutics; CMO: (consultant/speaker's fees) Abivax, Genentech, RegenBio, MCure