



M. DUBINSKY<sup>1</sup>, S. DANESE<sup>2</sup>, D. T. RUBIN<sup>3</sup>, B. E. SANDS<sup>4</sup>, M. GREGUS<sup>5</sup>, A. ARMUZZI<sup>6</sup>, G. D'HAENS<sup>7</sup>, U. SEIDLER<sup>8</sup>, X. TRETON<sup>9</sup>, C. J. RABAT<sup>10</sup>, J. T. FINE<sup>10</sup>, K. SHAN<sup>10</sup>, C. M. DOLAN<sup>11</sup>, D. JACOBSTEIN<sup>10</sup>, F. CATALDI<sup>10</sup>, B. SIEGMUND<sup>12</sup>

<sup>1</sup>Mount Sinai Kravis Children's Hospital, New York, NY, USA; <sup>2</sup>IRCCS Ospedale San Raffaele, Milan, Italy; <sup>3</sup>University of Chicago School of Medicine, Chicago, IL, USA; <sup>4</sup>Icahn School of Medicine at Mount Sinai, New York, NY, USA; <sup>5</sup>KM Management spol. s.r.o., Nitra, Slovakia; <sup>6</sup>IRCCS Humanitas Research Hospital, Milan, Italy; <sup>7</sup>Amsterdam University Medical Center, Amsterdam, the Netherlands; <sup>8</sup>Medizinische Hochschule Hannover, Hannover, Germany; <sup>9</sup>Institut des MICI, Neuilly-sur-Seine, France; <sup>10</sup>Abivax S.A., Paris, France; <sup>11</sup>CMD Consulting, Sandy, UT, USA; <sup>12</sup>Charité-Universitätsmedizin Berlin, Berlin, Germany

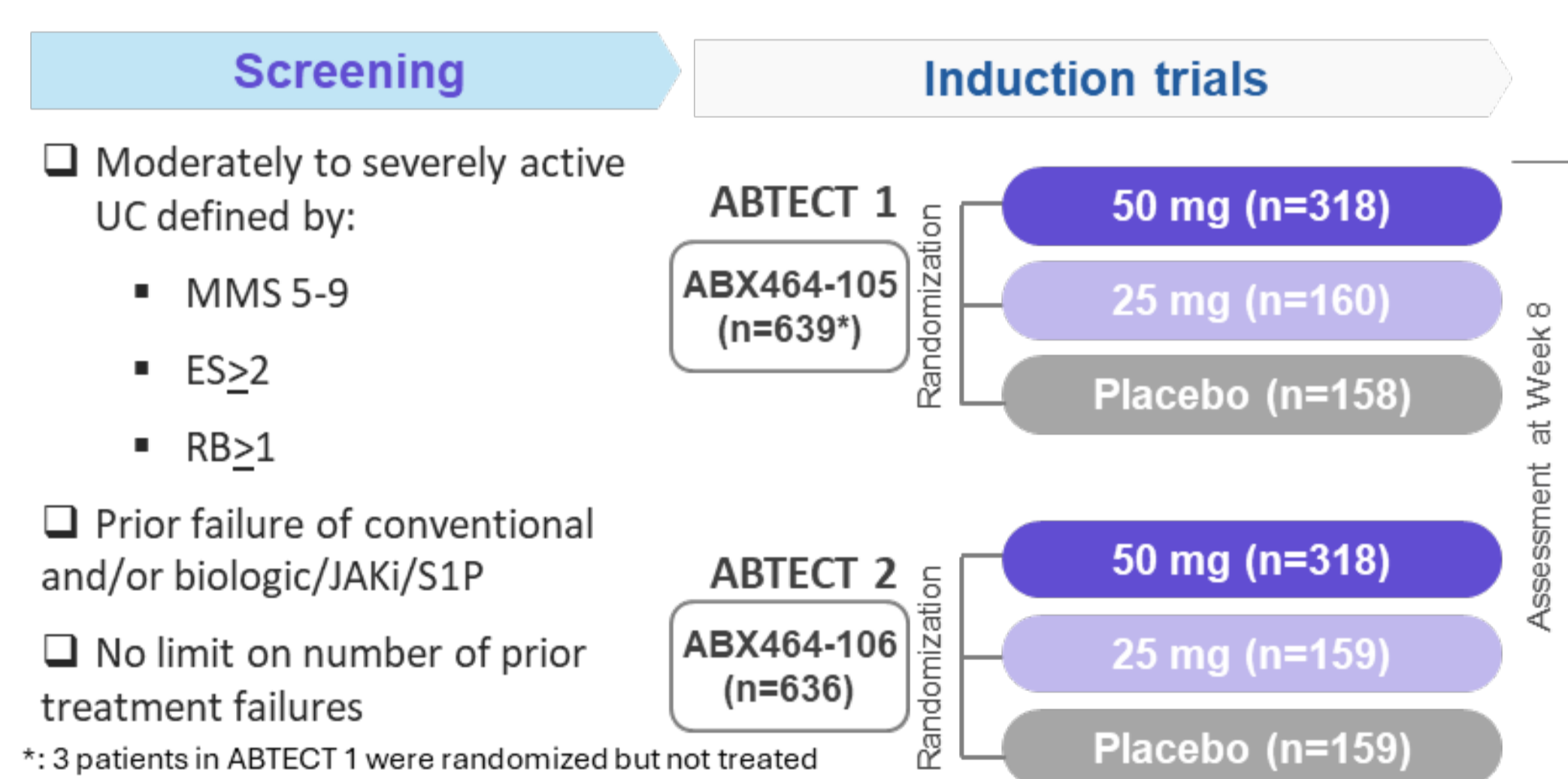
## INTRODUCTION

- 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)<sup>1-3</sup>.
- Pts with UC report fatigue as one of the major complaints which negatively impacts quality of life. Here we report efficacy data from two Phase 3, 8-week, induction trials on patient-reported fatigue.

## METHOD

- In the Phase 3 ABTECT 1 and ABTECT 2 trials, pts were randomized 2:1:1 to receive Obe 50 mg QD, Obe 25 mg QD, or placebo QD (PBO) for 8 weeks (Figure 1).

Fig. 1: Design of ABTECT induction trials



- Pts reported their fatigue using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) and Fatigue Numerical Rating Scale (NRS).<sup>4-6</sup>
- FACIT-F was assessed at baseline and week 8. FACIT-F includes 13 items that measure self-reported fatigue and its impacts on daily activities. Scores range from 52 to 0; higher scores indicate less fatigue.
- Meaningful within patient change (MWPC) is defined as a change of  $\geq 5$  points. FACIT-F remission is defined as a score of  $>40$ .<sup>7</sup>
- Fatigue NRS was collected in a daily electronic diary and pts rated fatigue on a scale from 0 to 10; higher scores indicate worse fatigue. Fatigue NRS remission is defined as a score of  $\leq 2$ .<sup>6</sup>

## REFERENCES

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## DISCLOSURES

MD (consultant or speaker's fees) Abbvie, Abivax, Arena Pharmaceuticals, AstraZeneca, Boehringer Ingelheim International GmbH, Bristol-Myers 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, Celltrion, Sandoz, Boehringer Ingelheim; DT (consultant or speaker's fees) Abbvie, Abivax SA, Altrubio, Athos Therapeutics, Inc, Bristol-Myers Squibb, Celltrion, Connect BioPharma, Eli Lilly & Co., Genentech (Roche) Inc., Iterative Health, Janssen Pharmaceuticals, Johnson & Johnson, Merck & Co., Odyssey Therapeutics, Pfizer, Sanofi, Spivac, Takeda Pharmaceuticals, Vedanta Biosciences, and Ventiv (Grant) Takeda; BE (consultant or speaker's fees) Abivax, Adiso Therapeutics, Agomab, Alimentiv, Amgen, Arena Pharmaceuticals, Artizon Biosciences, Artogen Therapeutics, AstraZeneca, Bacalin Therapeutics, Biora Therapeutics, Boehringer Ingelheim, Boston Pharmaceuticals, Bristol Myers Squibb, Calix, Celltrion, ClostrBio, Connect BioPharm, Cyclo Pharma, Eli Lilly and Company, Entera, Evonimmune, Ferring, Fresenius Kabi, Galapagos, Gilead Sciences, Genentech, GlaxoSmithKline, Gossamer Bio, HMP Acquisition, Imhotep, Immunix, Index Pharmaceuticals, Innovation Pharmaceuticals, Janssen, Johnson & Johnson, Kaleido, Kalypso, Merck, MicroBio, Morphic Therapeutic, MRM Health, OSE Immunotherapeutics, Pfizer, Pragenity, Prometheus Biosciences, Prometheus Laboratories, Protagonist Therapeutics, Takeda, Target RWE, Theravance Biopharma #8D, TLL Pharmaceutical, USNM Enterprises, Ventyx Biosciences, Vela Bio, and stock options from Ventyx Biosciences; MG (consultant or speaker's fees) Abbvie, Janssen, Pfizer; Expert advisor: Abbvie, Eli Lilly, Takeda, Zentiv; AA (consultant or speaker's fees) Abivax, Alfa Sigma, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Celltrion, Eli Lilly, Entera, Ferring, Galapagos, Gilead, Giuliani, Janssen, LionHeath, MSD, Nestlé, Pfizer, Protagonist Therapeutics, Roche, Samsung Bioepis, Sanofi, Sandoz, Takeda, Teva Pharmaceuticals, Tillots Pharma, AG Pharma, Novartis; (Grant) Biogen, MSD, Takeda, and Pfizer; GDH (consultant or speaker's fees) Abbvie, Abivax, Agomab, Alimentiv, Anaptys Bio, AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim, Celltrion, Eli Lilly, Exellion Biosciences, Galapagos, GlaxoSmithKline, Dr Falk Pharma, Pfizer, J&J, Merck, Mirador, Polpharma, Proscia Diagnostics, Sorriso Pharma, Spyre, Takeda, Ventyx (Grant) Pfizer, BMS, J&J, Abbvie, Alimentiv BV, Eli Lilly, Takeda, Prometheus Laboratories; 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; BS (consultant or speaker's fees) Abbvie, Celltrion, MSD, J&J, Takeda, Amgen, Alphasigma, Lilly, Thabor Therapeutics; BS (consultant or speaker's fees) Abbvie, Altrubio, Abivax, Boehringer Ingelheim, BMS, Dr. Falk Pharma, Eli Lilly, Endpoint Health, Falk, Galapagos, Janssen/Johnson&Johnson, Matera Prima, Pfizer, and Takeda; AlfaSigma, CED Service GmbH, MSD, Trix bio (Grant) Pfizer; CMD (consulting fees): Abivax, Genentech, RegenBio, MCRU.

## RESULTS

A total of 1272 pts were randomized and treated in ABTECT-1 (n=636) and ABTECT-2 (n=636). Of these, 747 pts completed the FACIT-F at Baseline, and 1241 pts completed the Fatigue NRS at baseline and were included in this analysis.

### FACIT-F: Obefazimod Treatment Improves Patient-Reported Fatigue at Week 8

- At week 8, a greater percentage of pts treated with Obe achieved remission of fatigue (a score of  $>40$  points) as measured by the FACIT-F compared to placebo (Figure 2).
- A greater percentage of pts treated with Obe achieved MWPC (a change of  $\geq 5$  points in the FACIT-F score) compared to placebo (Figure 3).
- Pts treated with Obe reported greater improvement in fatigue compared to placebo (Figure 4).

Fig. 2: Percent of patients with fatigue remission ( $>40$ ) as measured by the FACIT-F at Week 8

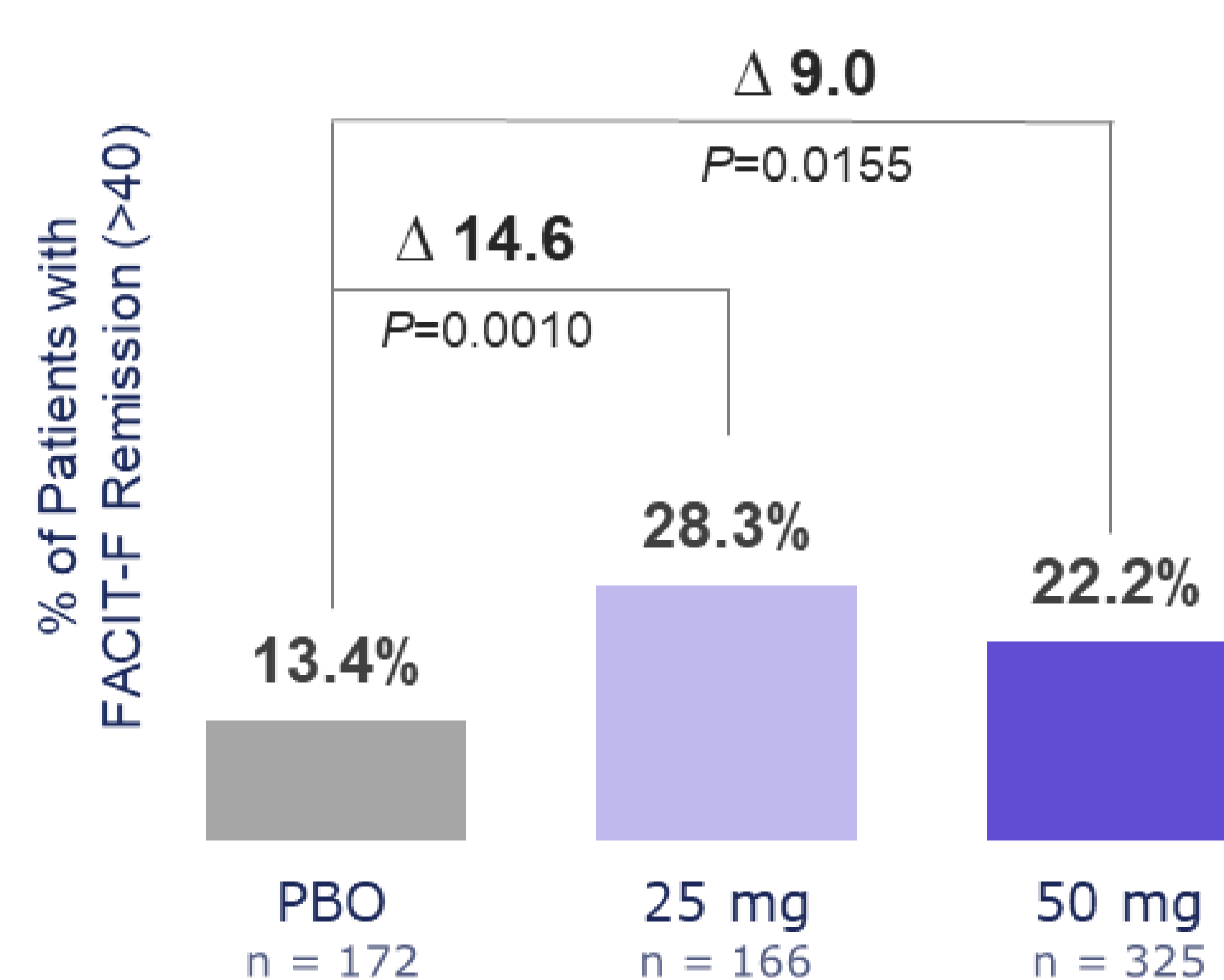


Fig. 3: Percent of patients with clinically meaningful change ( $\geq 5$ ) on the FACIT-F at Week 8

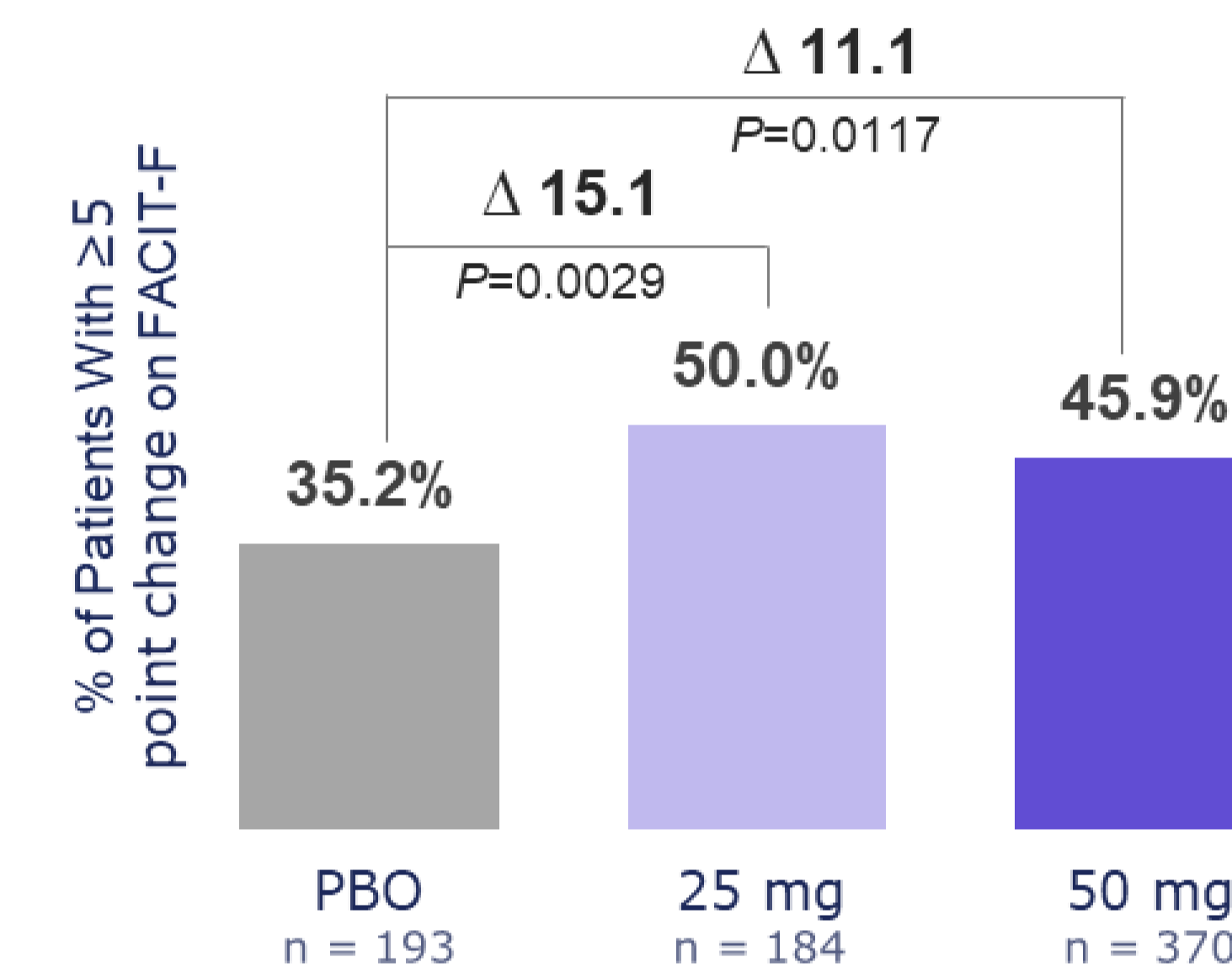
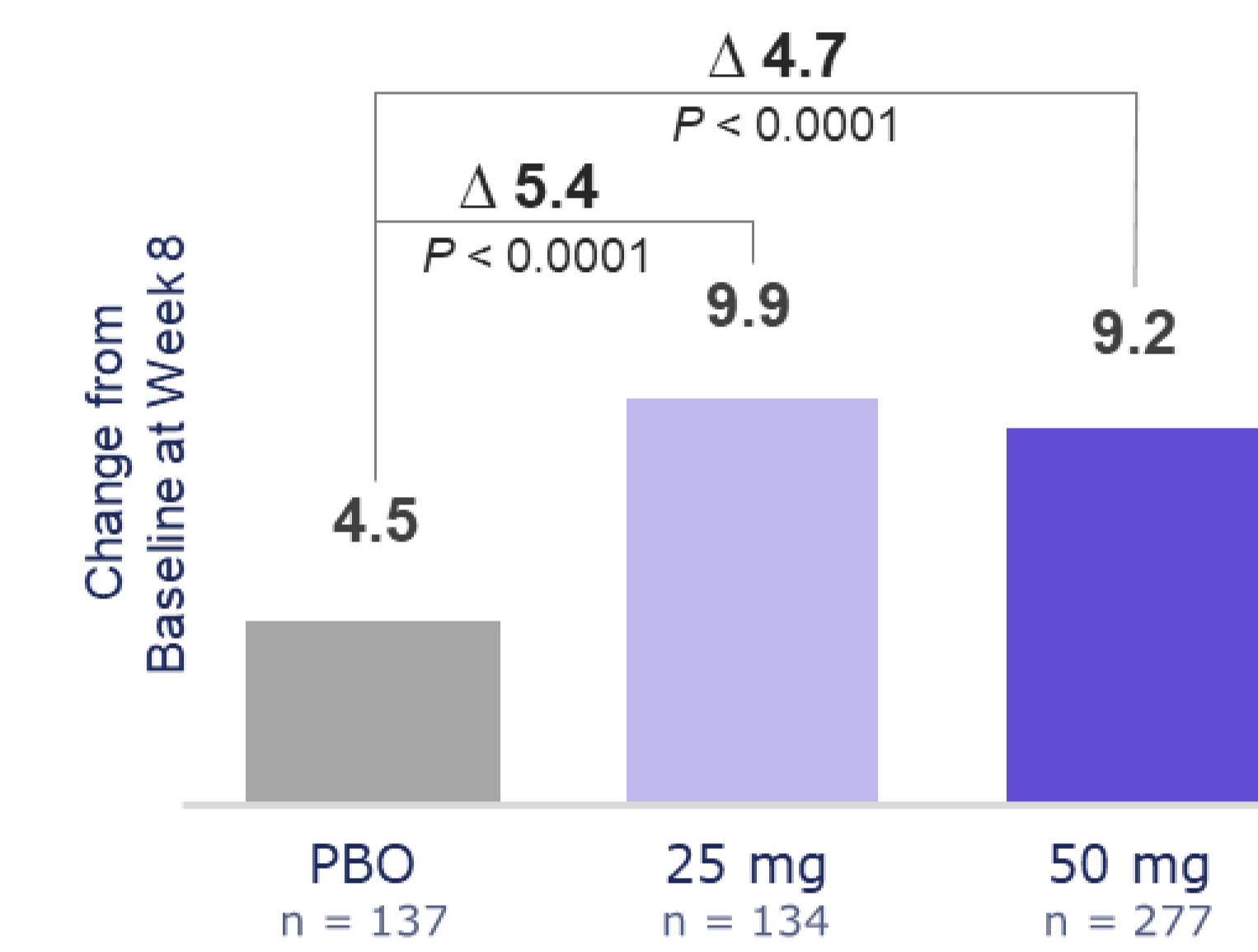


Fig. 4: Mean change in FACIT-F scores (range 0-52) from Baseline to Week 8



### Fatigue NRS: Obefazimod Treatment Improves Patient-Reported Fatigue at Week 8

- At Week 8, a greater proportion of pts treated with Obe had a remission of fatigue ( $\leq 2$ ) as measured by the Fatigue NRS compared to placebo (Figure 5). Results were observed as early as Week 2 (Figure 6).
- At Week 8, pts treated with Obe showed greater reductions in Fatigue NRS scores compared with placebo (Figure 7), with nearly twice the decrease observed versus placebo.

Fig. 5: Percent of patients with Fatigue NRS remission ( $\leq 2$ ) at Week 8

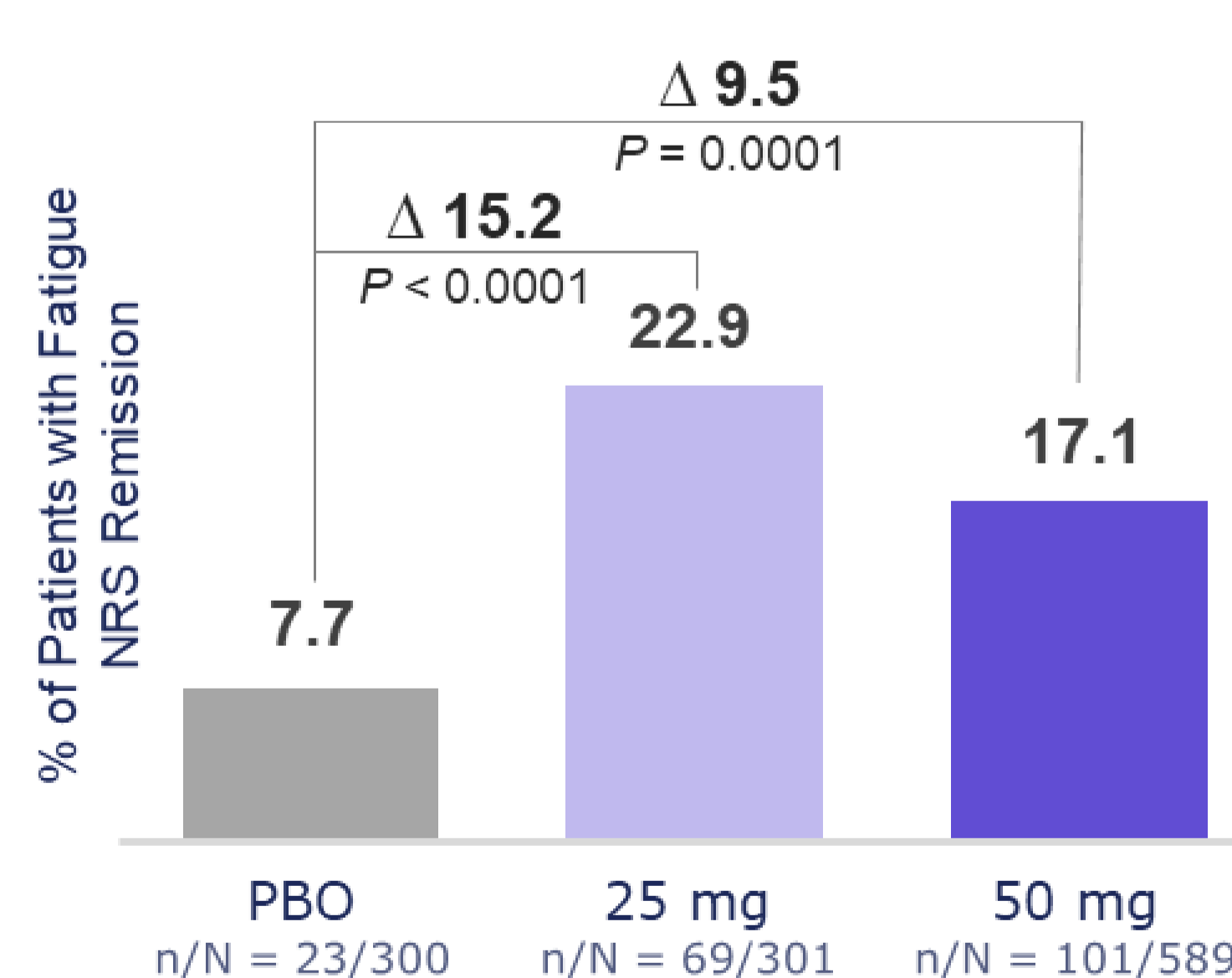


Fig. 6: Mean change in Fatigue NRS scores from Baseline to Weeks 1-8

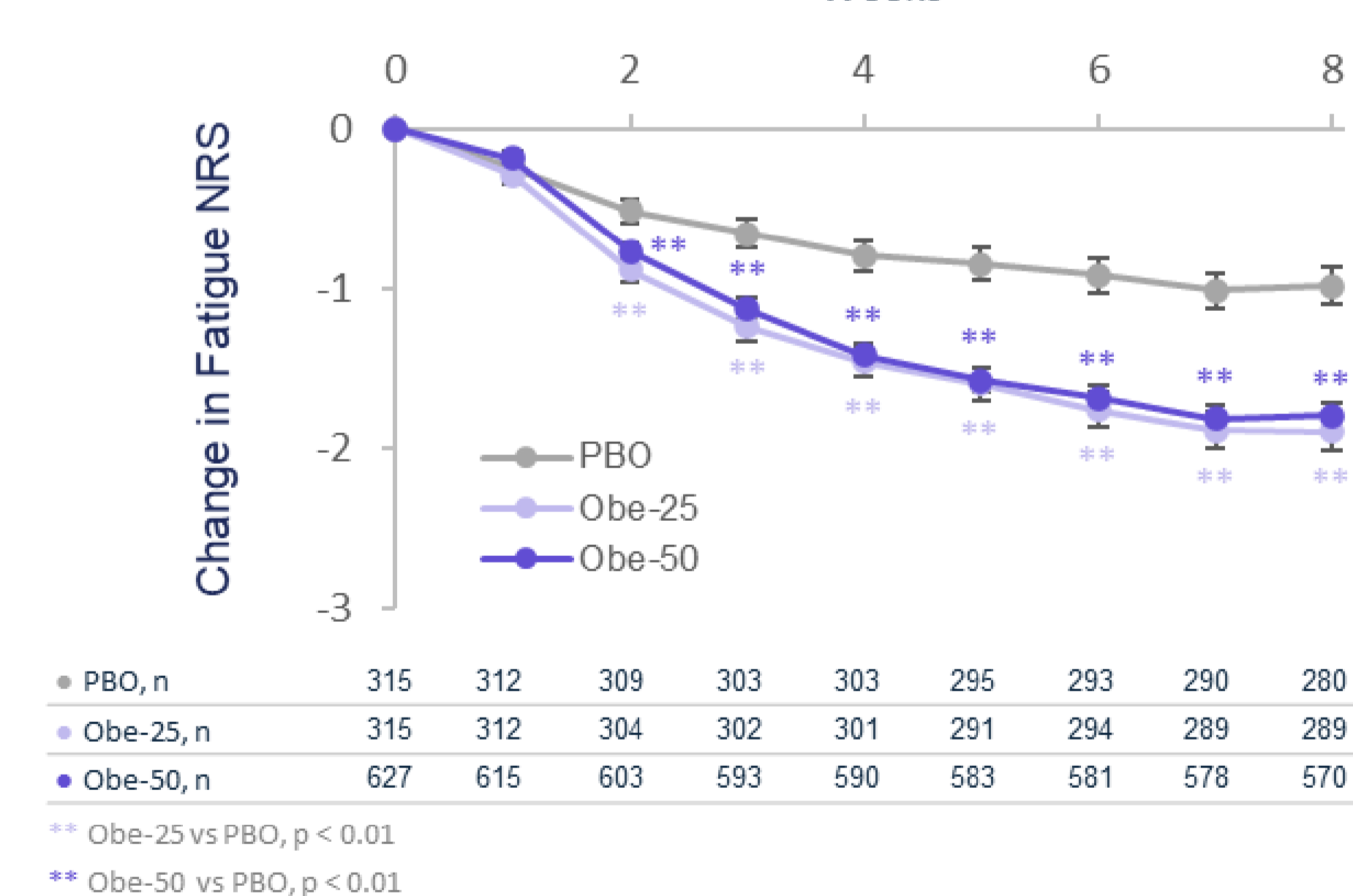
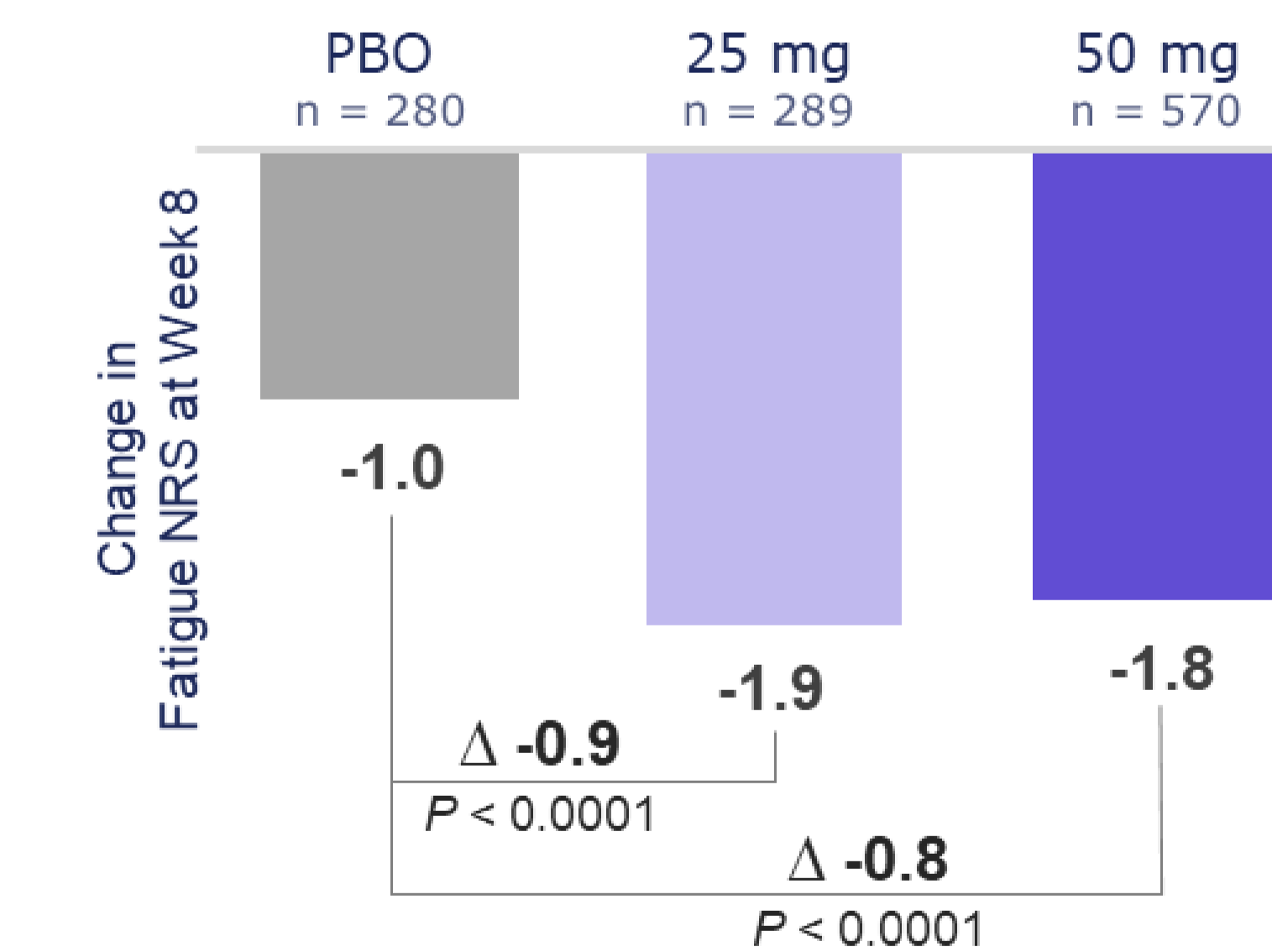


Fig. 7: Mean change in Fatigue NRS scores (range 0-10) from Baseline to Week 8



## CONCLUSIONS

- Patients with moderately to severely active UC treated with obefazimod reported marked improvements in fatigue measured by FACIT-F and the Fatigue NRS across both ABTECT induction trials
- Patients reported improvements in fatigue as early as 2 weeks after initiating treatment

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7-11 Blvd Haussmann - 75009 Paris, France  
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