

# Obefazimod induction therapy for moderately to severely active ulcerative colitis: pooled analysis of inflammatory biomarkers from the two ABTECT Phase 3 double-blind, placebo-controlled induction trials

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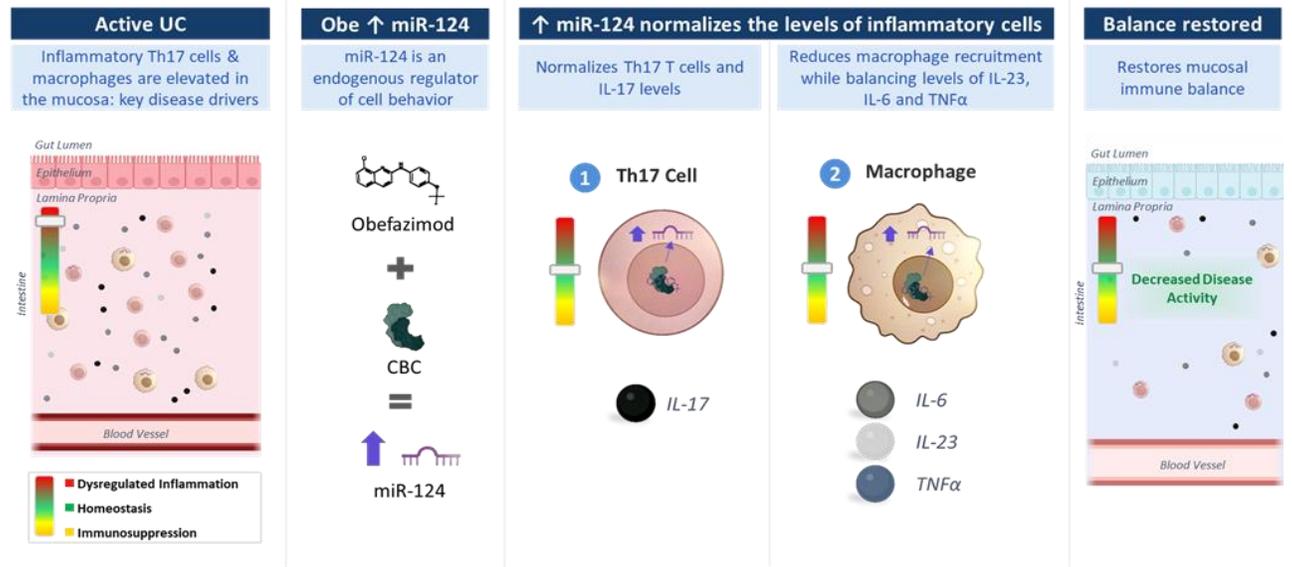
# Disclosure of Conflicts of Interest

## **Consulting and/or speaking fees from:**

AbbVie, Abivax, AlfaSigma, Boehringer Ingelheim, Bristol Myers Squibb, CED Service GmbH, Dr. Falk Pharma, Eli Lilly, Endpoint Health, Falk, Ferring, Galapagos, Gilead, Janssen, Landos, Materia Prima, PredictImmune, MSD, Pfizer, Takeda, Tr1x bio.

# Obefazimod MOA

Obefazimod restores mucosal immune balance in ulcerative colitis (UC) through regulation of Th17 cells and macrophages

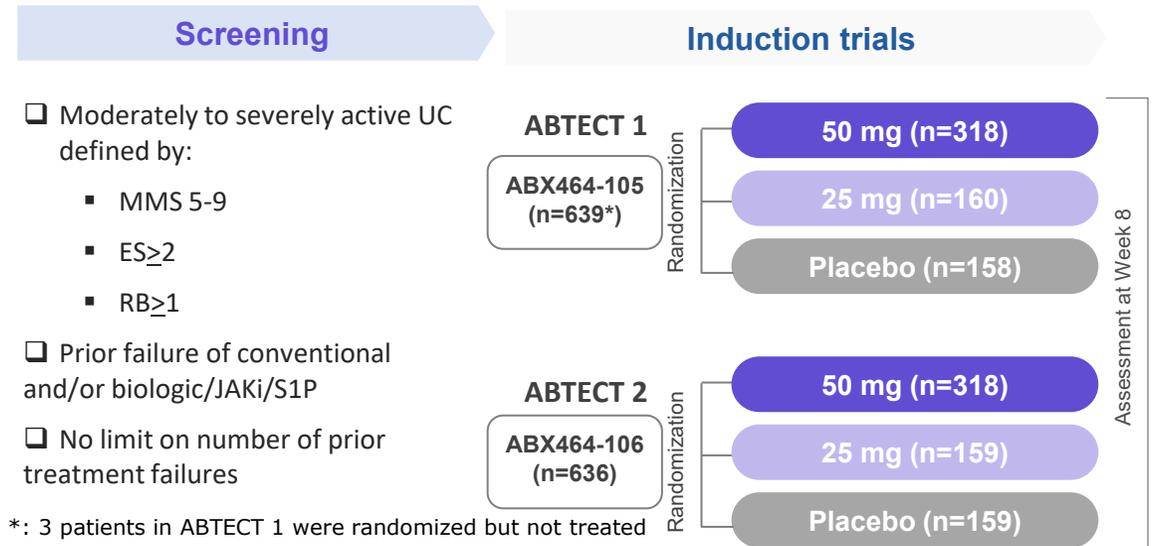


Apolit et al. Clin Transl Gastroenterol, 2023 | Vermeire et al., J Crohns Colitis, 2023 | Abivax Data on File | Images made with BioRender

## Design of ABTECT induction trials

This presentation describes a pooled analysis of inflammatory biomarkers:

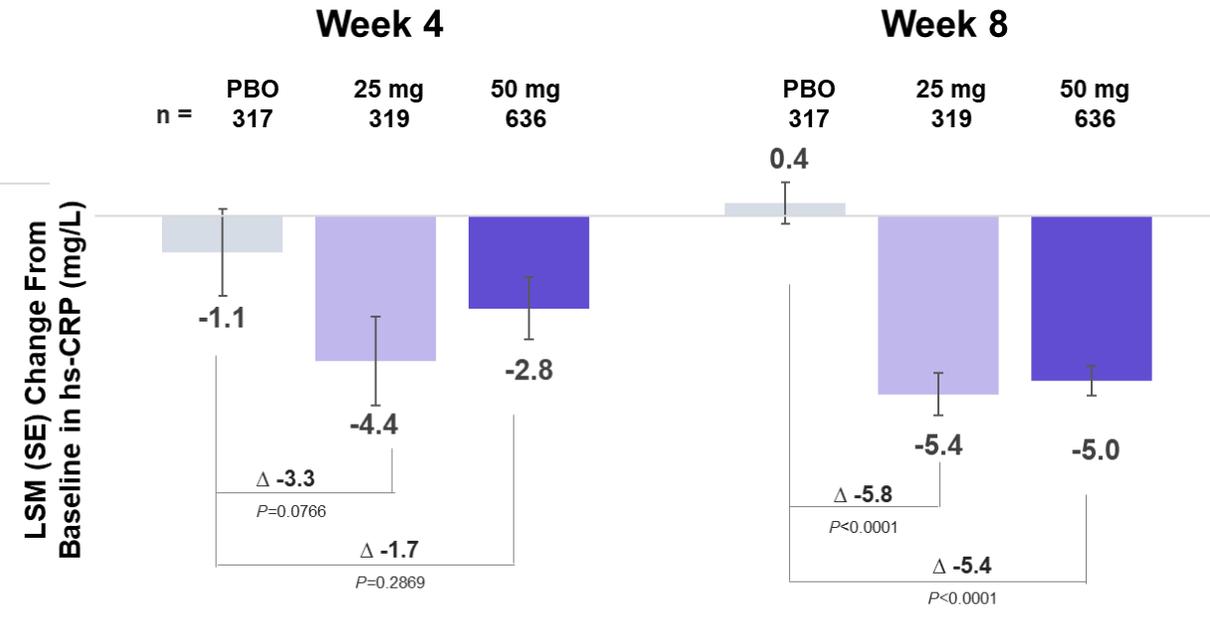
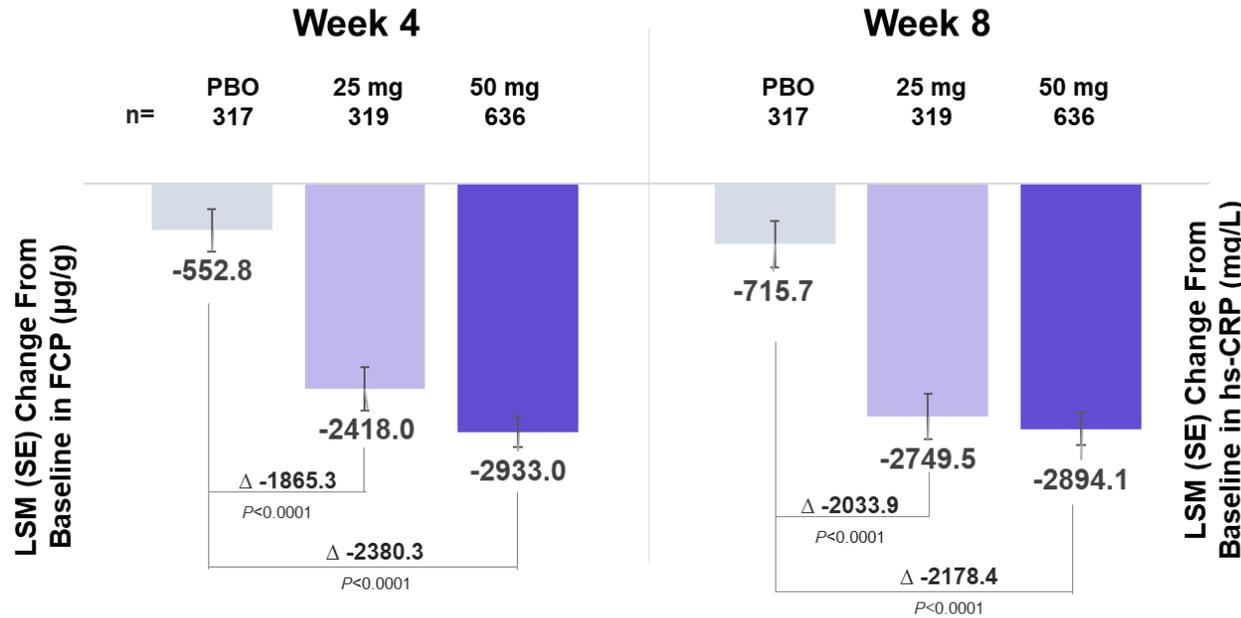
- Fecal calprotectin (FCP)
- High-sensitivity C-reactive protein (hs-CRP)



\*: 3 patients in ABTECT 1 were randomized but not treated

## FCP Change From Baseline (µg/g)

## hs-CRP Change From Baseline (mg/L)



Baseline FCP, mean (SD), µg/g

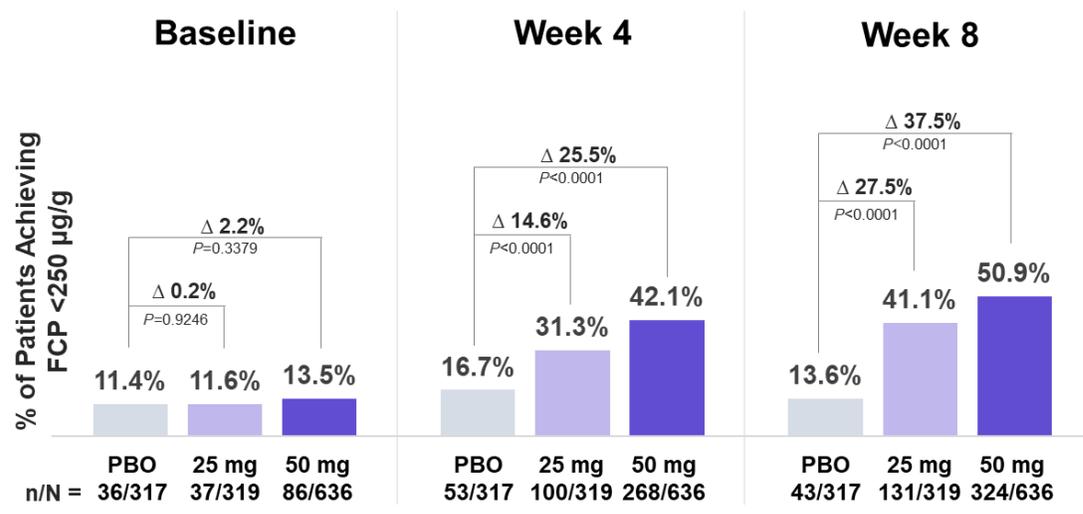
| PBO (n=317)     | Obe25 (n=319)   | Obe50 (n=636)   |
|-----------------|-----------------|-----------------|
| 4918.3 (8756.6) | 3312.1 (5683.4) | 3763.6 (6932.9) |

Baseline hs-CRP, mean (SD), mg/L

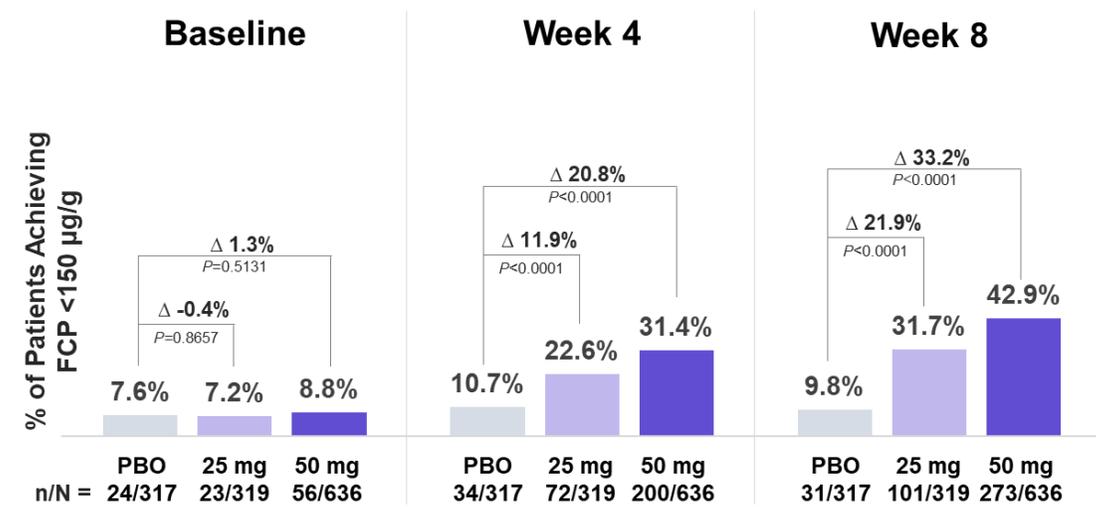
| PBO (N=317) | Obe25 (N=319) | Obe50 (N=636) |
|-------------|---------------|---------------|
| 12.0 (21.8) | 8.4 (13.1)    | 10.3 (20.0)   |

FCP, fecal calprotectin; hs-CRP, high-sensitivity C-reactive protein; LS, least square; MMRM, mixed model for repeated measures. \*Estimates are from MMRM model with log-transformed FC change from baseline value as the dependent variable; fixed categorical effects for treatment, visit, treatment-by-visit interaction, and randomization stratification factors (inadequate response to advanced therapies [yes/no]; and baseline oral corticosteroids usage [yes/no]), as well as a fixed continuous effect for the log-transformed baseline FC or hs-CRP value. An unstructured covariance matrix is used to model the within-subject variance-covariance structure. Results are back-transformed to the original scale for presentation. The LS mean % Difference is for Obe relative to placebo. P values are 2-sided. Assessments that occurred after any IE are considered missing. Baseline is the last nonmissing measurement taken on or prior to the start of study treatment. Baseline value as the dependent variable; fixed categorical effects for treatment, visit, treatment-by-visit interaction, and randomization stratification factors (inadequate response to advanced therapies [yes/no]; and baseline oral corticosteroids usage [yes/no]), as well as a fixed continuous effect for the log-transformed baseline FC or hs-CRP value. An unstructured covariance matrix is used to model the within-subject variance-covariance structure. Results are back-transformed to the original scale for presentation. The LS mean % Difference is for Obe relative to placebo. P values are 2-sided. Assessments that occurred after any IE are considered missing. Baseline is the last nonmissing measurement taken on or prior to the start of study treatment.

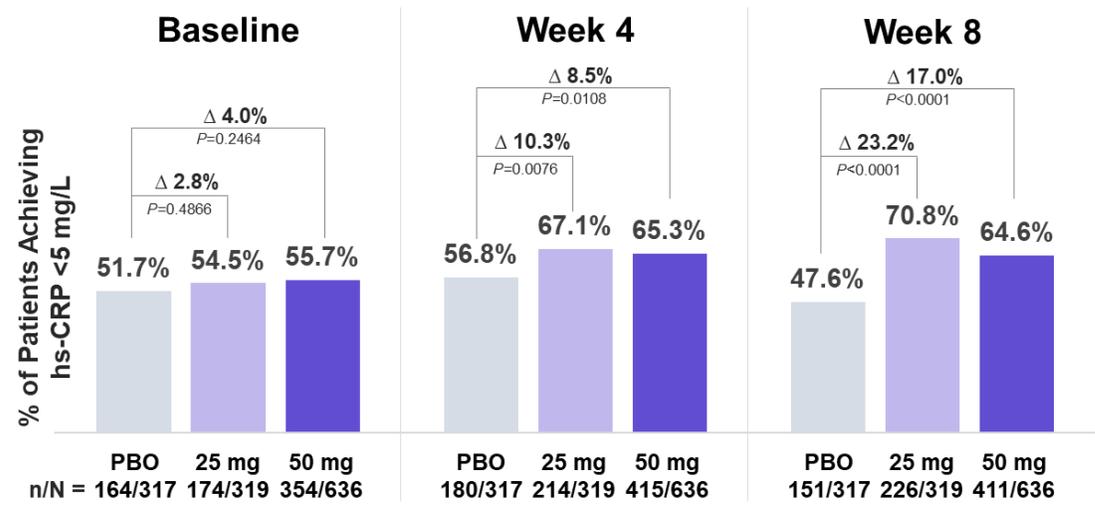
## FCP <250 µg/g



## FCP <150 µg/g



## hs-CRP <5 mg/L



FCP, fecal calprotectin; hs-CRP, high-sensitivity C-reactive protein; LS, least square; MMRM, mixed model for repeated measures. <sup>a</sup>Estimates are from MMRM model with log-transformed FC change from baseline value as the dependent variable; fixed categorical effects for treatment, visit, treatment-by-visit interaction, and randomization stratification factors (inadequate response to advanced therapies [yes/no]; and baseline oral corticosteroids usage [yes/no]), as well as a fixed continuous effect for the log-transformed baseline FC or hs-CRP value. An unstructured covariance matrix is used to model the within-subject variance-covariance structure. Results are back-transformed to the original scale for presentation. The LS mean % Difference is for Obe relative to placebo. P values are 2-sided. Assessments that occurred after any IE are considered missing. Baseline is the last nonmissing measurement taken on or prior to the start of study treatment. Baseline value as the dependent variable; fixed categorical effects for treatment, visit, treatment-by-visit interaction, and randomization stratification factors (inadequate response to advanced therapies [yes/no]; and baseline oral corticosteroids usage [yes/no]), as well as a fixed continuous effect for the log-transformed baseline FC or hs-CRP value. An unstructured covariance matrix is used to model the within-subject variance-covariance structure. Results are back-transformed to the original scale for presentation. The LS mean % Difference is for Obe relative to placebo. P values are 2-sided. Assessments that occurred after any IE are considered missing. Baseline is the last nonmissing measurement taken on or prior to the start of study treatment.

# Conclusions

- This pooled analysis of the two ABTECT induction trials provides evidence that both doses of obefazimod led to a rapid reduction of inflammatory biomarkers in patients with moderate to severe UC.