DDW2026
Digestive Disease Week®
MAY 2–5, 2026 | CHICAGO, IL
EXHIBIT DATES: MAY 3–5, 2026

Obefazimod enhances miR-124 expression in blood and colon tissue and reduces the key inflammatory cytokines IL-17A and IL-6 in serum of patients with moderate-to-severely active ulcerative colitis: results from the Phase 3 ABTECT induction trials

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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].
- We assessed the effects of Obe on miR-124 expression in blood and colon tissue and serum cytokine levels from patients at baseline and week 8 of the ABTECT trials.

METHOD

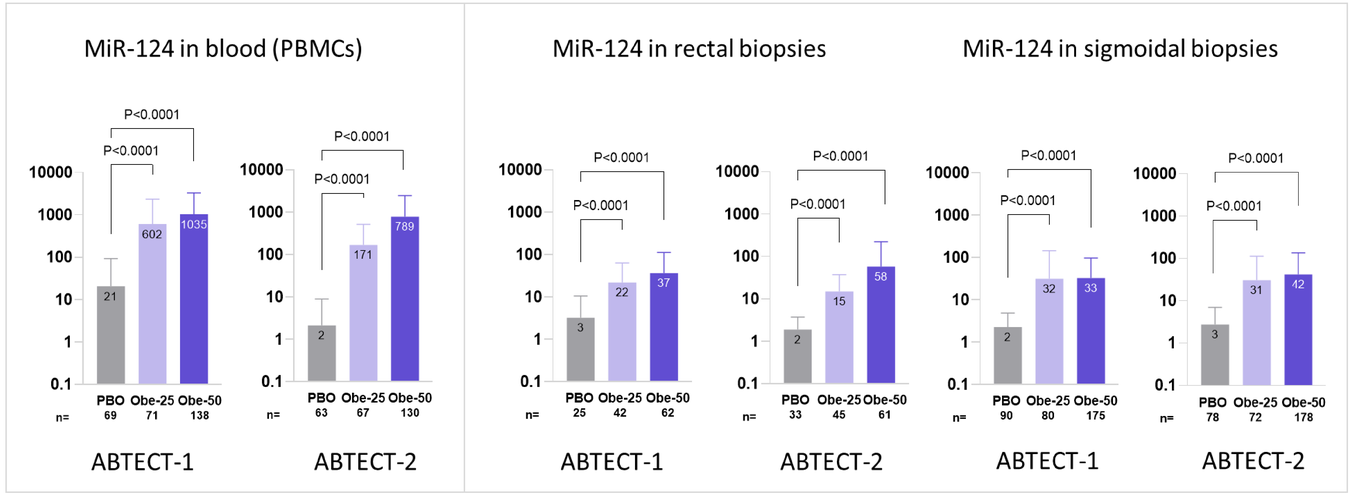
- In the ABTECT trials, absolute quantification of miR-124 copy number was performed at baseline and week 8 using droplet digital PCR (ddPCR; QuantaSoft Pro).
- Fold change in miR-124 was available in 268 pairs of rectal and 673 pairs of sigmoidal biopsy samples, as well as 538 pairs of whole blood from patients receiving Obe-25 mg, Obe-50 mg, or placebo (PBO).
- Cytokines IL-17A and IL-6 were measured by ELLA 5-plex (Biotechne) and S-Plex Human (MSD), respectively in 1126 and 1110 pairs of serum samples at baseline and week 8 for IL-6 and IL-17A, respectively.

RESULTS

- In both Phase 3 ABTECT trials, Obe-25 and 50 mg significantly enhanced expression of miR-124 in blood (unadjusted p < 0.0001 vs. PBO) and in rectal and sigmoidal tissue at week 8 relative to PBO (unadjusted p < 0.0001 vs. PBO) (Fig. 1).
- In both ABTECT trials, Obe-25 and 50 mg significantly reduced IL-17A levels in serum at week 8 compared with PBO (unadjusted p < 0.0001) (Fig. 2).
- IL-6 levels were also decreased by Obe-25 (unadjusted p = 0.0150) and Obe-50 (unadjusted p = 0.0039) in serum of pts from ABTECT-1 and ABTECT-2 in comparison to PBO, respectively (Fig. 2).

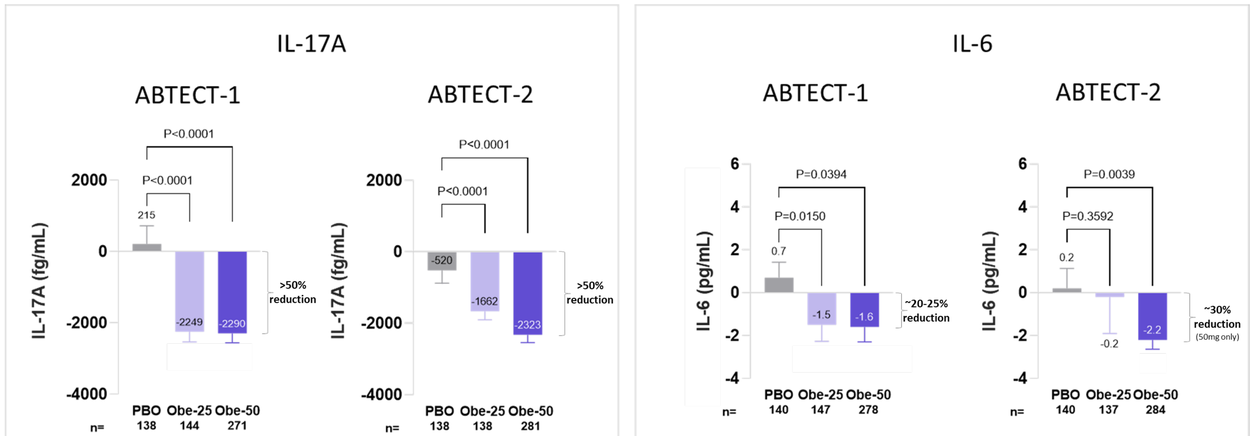
The physiologic miR-124-based mechanism allows partial reduction of inflammatory cytokines IL-17A and IL-6 towards homeostatic levels without the complete blockade of these pathways as demonstrated with direct IL-17 or IL-6 inhibitors, respectively.

Fig. 1: miR-124 expression in blood and colon tissues at week 8 in patients with UC - ABTECT-1 and ABTECT-2 trials



For miR-124, estimates are from ANCOVA model with treatment and randomization stratification factors (inadequate response to advanced therapies -ATIR (yes/no), baseline oral corticosteroids - CS (yes/no), and for ABTECT-2 only, region (Japan/rest of world) as fixed factors, and log10-transformed baseline value as a covariate. P-values are two-sided and obtained using Dunn's Test.

Fig. 2: IL-17A and IL-6 changes from baseline to week 8 (mean ± SE) in serum from patients with UC - ABTECT-1 and ABTECT-2 trials



Baseline Levels (fg/mL)			
Dose	Pbo	25mg	50mg
Mean	4242	3684	3787
Median	2709	2462	2540

Baseline Levels (fg/mL)			
Dose	Pbo	25mg	50mg
Mean	3961	3297	3759
Median	2662	2428	2369

Baseline Levels (pg/mL)			
Dose	Pbo	25mg	50mg
Mean	6.0	5.4	7.1
Median	4.2	3.5	3.7

Baseline Levels (pg/mL)			
Dose	Pbo	25mg	50mg
Mean	7.1	6.1	6.1
Median	4.0	3.8	4.0

For cytokines, estimates are from a MMRM model with fixed categorical effects for treatment, visit, treatment-by-visit interaction and randomization stratification factors (ATIR (yes/no), baseline oral CS (yes/no), and for ABTECT-2 only, region (Japan/rest of world), as well as a fixed continuous effect for the baseline value of the outcome of interest. An unstructured covariance matrix is used to model the within-subject variance-covariance structure. P-values are two sided.

CONCLUSIONS

- **In the ABTECT induction trials conducted in pts with UC, obefazimod was associated with enhanced expression of miR-124 and nominally significant reductions in the pro-inflammatory cytokines IL-17A and IL-6 towards balanced levels.**
- **These findings confirm preclinical and Phase 2 trial observations and reflect restoration of immune homeostasis.**
- **Analysis of the translational mechanism of obefazimod is ongoing in the ABTECT Maintenance trial (NCT05535946) in pts with moderate-severe UC and the ENHANCE-CD trial (NCT06456593) in pts with moderate-severe Crohn's disease.**

REFERENCES

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DISCLOSURES

BS (consultant or speaker's fees) AbbVie, AltruBio, Abivax, Boehringer Ingelheim, Dr. Falk Pharma, Eli Lilly, Endpoint Health, Falk, Galapagos, Gilead, Janssen, Landos, Materia Prima, PredictImmune, Pfizer, Takeda, AlfaSigma, BMS, CED Service GmbH, MSD, Ferring, Tr1x bio (Grants) Pfizer; 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; MD (consultant or speaker's fees) Abbvie, Abivax, Arena Pharmaceuticals, Astra Zeneca, Boehringer Ingelheim International GmbH, Bristol-Meyer Squibb, Eli Lilly and Company, F. Hoffmann-La Roche Ltd, Genentech Inc, Gilead, Janssen Pharmaceuticals, Merck, Pfizer Inc, Prometheus Biosciences, Takeda Pharmaceuticals; RA (consultant or speaker's fees) AbbVie, Abivax, AstraZeneca, Bristol-Myers Squibb, Celltrion Healthcare, Galapagos, J&J, Lilly, MSD, Pfizer, and Takeda Pharma; BV (consultant or speaker's fees) Abbvie, Agomab, Alfasigma, Biogen, BMS, Celltrion, Eli Lilly, Falk, Ferring, Galapagos, Materia Prima, J&J, Pfizer, Sandoz, Takeda, Tillots Pharma, Truvion and Viatris, Alimentiv, Anaptys Bio, Applied Strategic, Astrazeneca, Atheneum, BenevolentAI, Biora Therapeutics, Boxer Capital, BMS, Domain Therapeutics, Guidepont, Landos, Merck, Mirador Therapeutics, Mylan, Nxera, Inotrem, Ipsos, Sanofi, Santa Ana Bio, Sapphire Therapeutics, Sosei Heptares, Viatris (Grant) AbbVie, Biora Therapeutics, Celltrion, Landos, Pfizer, Sanofi, Sossei Heptares/Nxera, Takeda (Stock options) Vagustim, Thethis Pharma; GDA (consultant or speaker's fees) Abbvie, Abivax, Agomab, Alimentiv, Anaptys Bio, AstraZeneca, Bristol Meiers Squibb, Boehringer Ingelheim, Celltrion, Eli Lilly, Exeliom Biosciences, Galapagos, Glaxo Smith Kline, Dr Falk Pharma, Pfizer, J&J, Merck, Mirador, Polpharma, Procise Diagnostics, Prometheus Biosciences, Sorriso Pharma, Spyre, Takeda, Ventyx (Grant) Pfizer, BMS, J&J, Abbvie, Alimentiv BV, Eli Lilly, Takeda, Prometheus Laboratories; PSD (consultant) Abbvie, Abivax, Adiso, Alimentiv, Bristol Meyer Squibb, Celltrion, Genentech, Geneoscopy, Janssen, Pfizer, Takeda

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