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Efficacy of obefazimod in patients with moderately to severely active ulcerative colitis: results in subgroups of prior inadequate response to advanced therapy (ATIR) including or excluding patients with prior JAK-IR from ABTECT Phase 3 induction trials

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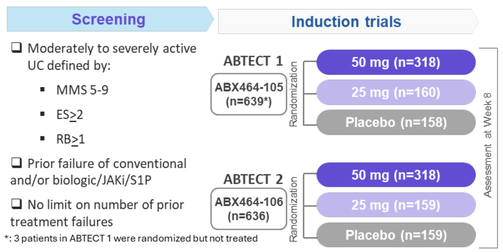
INTRODUCTION

- 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].
- In two 8-week induction ABTECT trials (NCT05507203, NCT05507216), Obe achieved clinically meaningful improvements in all clinical, endoscopic and histologic endpoints regardless of prior advanced therapy inadequate response (ATIR), including highly refractory pts with ≥4 prior treatment failures.
- This pooled analysis evaluates the impact of ATIR including and excluding pts with prior inadequate response to JAK inhibitors (JAK-IR) on the efficacy of Obe in the two ABTECT trials.

METHOD

- The multicenter, randomized, double-blind, placebo-controlled ABTECT trials enrolled pts with moderate-to-severe UC (MMS≥ 5, rectal bleeding sub-score (RBS) ≥ 1, centrally read endoscopic score (ES) ≥2) who had inadequate response, loss of response, or intolerance to at least one prior therapy (no upper limit), including corticosteroids, immunosuppressants, biologics, S1P receptor modulators and/or JAK inhibitors (Fig. 1).
- Pts were randomized 2:1:1 to Obe 50 mg QD (Obe-50), Obe 25 mg QD (Obe-25) or placebo (PBO) for 8 weeks.

Fig. 1: Design of ABTECT induction trials

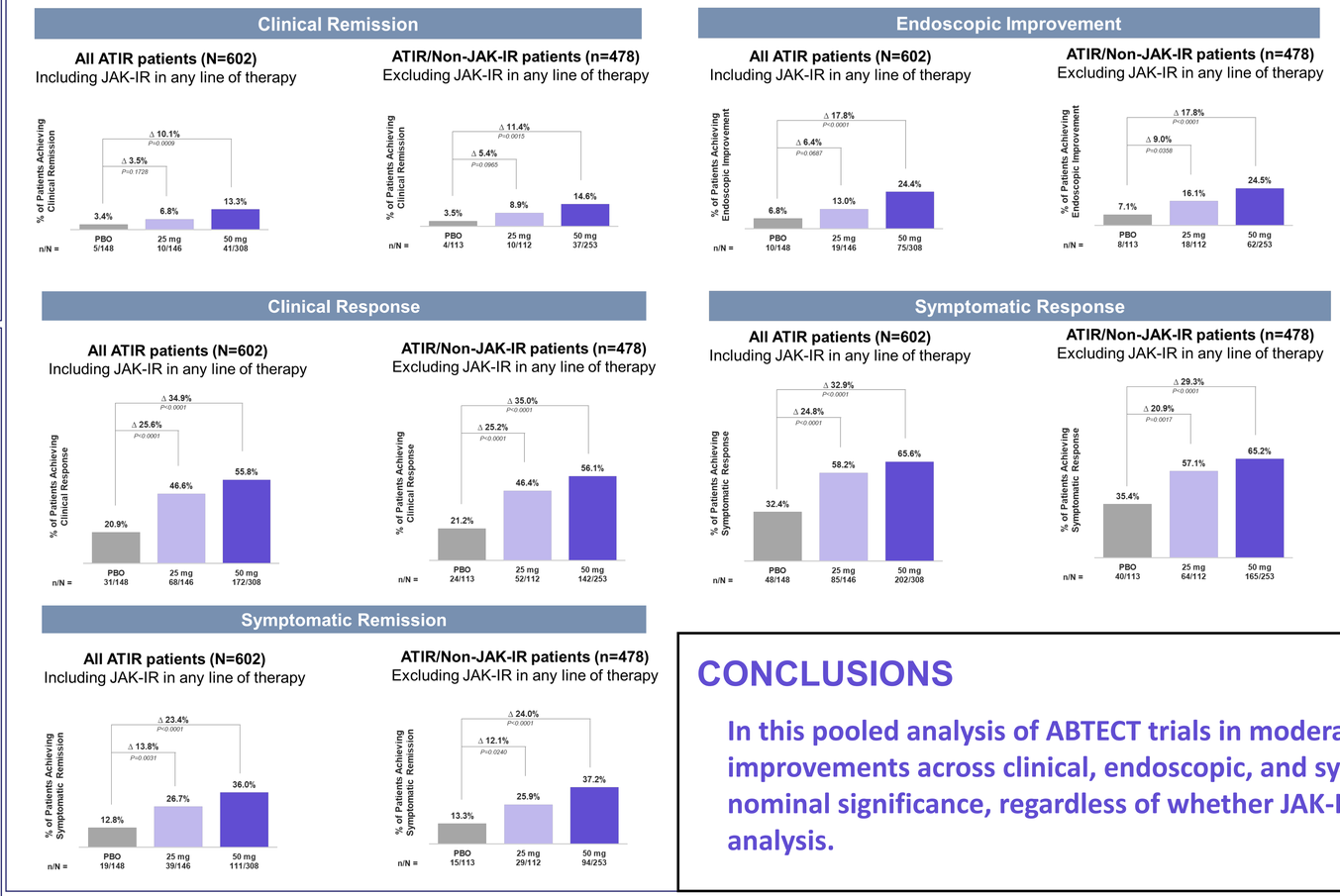


Rates of clinical remission and response, endoscopic improvement, symptomatic remission and response were compared across subgroups of all ATIR pts and the subgroup of ATIR pts without JAK-IR in any line of therapy (ATIR/Non-JAK-IR).

RESULTS

- Among 1272 pts treated in the ABTECT trials, 602 were ATIR and 478 ATIR/Non-JAK-IR. In both ATIR pts and in ATIR/Non-JAK-IR, Obe-50 led to nominally significant improvements at week 8 in clinical remission, clinical response, endoscopic improvement and symptomatic endpoints, compared with PBO (Fig. 2).
- Improvements were also observed with Obe-25, but with less consistency across efficacy endpoints.

Fig. 2: Eight-week induction efficacy of obefazimod in ATIR pts, including and excluding JAKi-IR in any line of therapy: pooled ABTECT-1 and ABTECT-2



Analyses not powered for statistical significance in subgroups; statistical inferences are exploratory, and all P values are nominal and 2-sided.
NRI is used for subjects with missing outcome at week 8 and subjects reporting any IE prior to week 8; % Difference is for Obe minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), baseline oral corticosteroids usage (yes/no).
Symptomatic response: reduction from baseline in pMMS of ≥1 point and a relative reduction from baseline in pMMS of ≥30%, and a reduction from baseline in RBS of ≥1 point and/or RBS ≤1. Clinical response: decrease from baseline in the MMS ≥2 points and ≥30% from baseline, plus a decrease in RBS ≥1 or an absolute RBS ≤1. Symptomatic remission: RBS=0, SFS ≤1. Endoscopic improvement: endoscopic subscore ≤1. Clinical remission: SFS=0 or 1, and RBS=0 and MES=0 or 1 (MES of 1 modified to exclude friability).
ATIR, advanced therapy inadequate response; IE, intercurrent event; JAK-IR, Janus kinase inhibitor inadequate response; MES, Mayo Endoscopic Subscore; MMS, Modified Mayo Score; NRI, non-responder imputation; pMMS, partial Modified Mayo Score; RBS, rectal bleeding subscore; SFS, stool frequency score.

CONCLUSIONS

In this pooled analysis of ABTECT trials in moderately to severely active UC, obefazimod led to improvements across clinical, endoscopic, and symptomatic endpoints in all ATIR pts with nominal significance, regardless of whether JAK-IR patients were included or excluded from the analysis.

REFERENCES

1: Vermeire S et al. *J Crohns Colitis*. 17: 1689-97, 2023 - 2: Vermeire S et al. *Gastroenterology*. 160: 2595-98, 2021 - 3: Vermeire S et al. *The Lancet Gastroenterology & Hepatology*. 7: 1024-35, 2022

DISCLOSURES

Disclosures : *FB (consultant or speaker's fees) AbbVie, Amgen, EG, J&J, Takeda, Abivax, Arena, BMS, Celltrion, Eli Lilly, Falk, Ferring, Fresenius, Galapagos, J&J, Pfizer, Sandoz, Vifor; DR (consultant or speaker's fees)* Abbvie, Abivax SA, Altrubio, Athos Therapeutics, Inc, Bristol-Myers Squibb, Celltrion, Connect BioPharma, Eli Lilly & Co., Genentech Inc., Iterative Health, Janssen Pharmaceuticals, J&J, Merck & Co., Odyssey Therapeutics, Pfizer, Sanofi, Spyre, Takeda Pharmaceuticals, Vedanta Biosciences, Ventyx (Grant) Takeda; *HT (consultant or speaker's fees) AbbVie, Calypso Biotech, Celtrion, Immunic, Pharmacosmos, Takeda Pharma, Biogen, BMS, Falk Foundation, Galapagos, J&J, Pfizer, Pharmacosmos; FDA (consultant or speaker's fees) Abbvie, Alfasigma, Ferring, Lilly, Sandoz, Janssen, Fresenius Kabi, Galapagos, Giuliani, MSD, Pfizer, Takeda, Tillotts, Omega Pharma, AnaptysBio, Nestlé; BES (consultant or speaker's fees) AbbVie, Abivax, Adiso Therapeutics, AgomAb, Alimentiv, Amgen, Arena Pharmaceuticals, Artizan Biosciences, Artugen Therapeutics, AstraZeneca, Bacainn Therapeutics, Biora Therapeutics, Boehringer Ingelheim, Boston Pharmaceuticals, Bristol Myers Squibb, Calibr, Celltrion, ClostraBio, Connect Biopharm, Cytoki Pharma, Eli Lilly and Company, Enthera, Evommune, Ferring, Fresenius Kabi, Galapagos, Gilead Sciences, Genentech, Glaxo SmithKline, Gossamer Bio, HMP Acquisition, Imhotex, Immunic, InDex Pharmaceuticals, Innovation Pharmaceuticals, Inotrem, Ironwood Pharmaceuticals, Janssen, Johnson & Johnson, Kaleido, Kalyope, Merck, MiroBio, Morphic Therapeutic, MRM Health, OSE Immunotherapeutics, Pfizer, Progenity, Prometheus Biosciences, Prometheus Laboratories, Protagonist Therapeutics, Q32 Bio, RedHill Biopharma, Sun Pharma Global, Surrozen, Synlogic Operating Company, Takeda, Target RWE, Theravance Biopharma R&D, TLL Pharmaceutical, USWM Enterprises, Ventyx Biosciences, Viela Bio, and stock options from Ventyx Biosciences.*

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