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Summary

EFFICACY OF OBEFAZIMOD IN ABTECT PHASE 3 INDUCTION TRIALS: RESULTS OF 8-WEEK THERAPY IN SUBSETS OF PATIENTS WITH AND WITHOUT PRIOR INADEQUATE RESPONSE TO ADVANCED THERAPIES

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Obefazimod 50 mg once daily demonstrated statistically significant clinical remission at week 8 in patients with moderate-to-severe ulcerative colitis regardless of prior advanced therapy exposure in the pooled ABTECT-1 and ABTECT-2 Phase 3 trials.

KEY POINTS

- In the pooled analysis, obefazimod 50 mg achieved clinical remission in 13.3% of advanced therapy-exposed patients versus 3.4% with placebo (difference 10.1%, p=0.0009) and in 27.7% of advanced therapy-naive patients versus 5.3% with placebo (difference 22.4%, p<0.0001).
- Clinical response was achieved in 55.8% of advanced therapy-exposed patients on obefazimod 50 mg versus 20.9% on placebo (difference 34.9%, p<0.0001) and in 68.0% of advanced therapy-naive patients versus 39.6% on placebo (difference 28.2%, p<0.0001).
- Obefazimod 50 mg showed consistent clinical response across all lines of therapy including patients with 4 or more advanced therapy failures and those who had failed JAK inhibitors.
- In advanced therapy-exposed patients, obefazimod 50 mg outperformed the 25 mg dose across efficacy measures, while both doses performed similarly in advanced therapy-naive patients.
- Obefazimod was well tolerated with a safety profile similar to previous studies across both dose levels and placebo.

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