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Summary

EFFICACY OF OBEFAZIMOD IN PHASE 3 ABTECT-MAINTENANCE TRIAL: RESULTS OF 44-WEEK THERAPY IN SUBSETS OF PATIENTS WITH AND WITHOUT PRIOR INADEQUATE RESPONSE TO ADVANCED THERAPIES

Bruce E. Sands

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Obefazimod, an oral once-daily microRNA-124 enhancer, demonstrated significant efficacy at week 44 of maintenance therapy in ulcerative colitis patients with and without prior advanced therapy failure, including those who failed JAK inhibitors.

KEY POINTS

- In patients with prior advanced therapy inadequate response (AT-IR-Yes), clinical remission rates were 34.2% for obefazimod 25 mg and 42.2% for 50 mg versus 6.9% for placebo (placebo-adjusted differences 28.0% and 33.1%, both p<0.0001).
- In advanced therapy-naive patients (AT-IR-No), clinical remission rates were 61.5% for 25 mg and 59.0% for 50 mg versus 12.5% for placebo (placebo-adjusted differences 48.1% and 45.1%, both p<0.0001).
- Among JAK inhibitor failures, clinical remission was achieved in 28.6% with 25 mg and 33.3% with 50 mg versus 0% with placebo (p=0.0190 and p=0.0375).
- Endoscopic remission (Mayo endoscopic score = 0) in AT-IR-Yes patients was 23.7% for 25 mg and 38.9% for 50 mg versus 5.6% for placebo (placebo-adjusted differences 17.3% and 31.3%, p=0.0049 and p<0.0001).
- Efficacy was observed across all treatment lines from zero to 4+ prior advanced therapy failures, with the 50 mg dose numerically more effective than 25 mg in patients with prior advanced therapy exposure.
- The trial enrolled patients with no upper limit on prior treatment lines, including corticosteroids, immunosuppressants, biologics, S1P receptor modulators, and JAK inhibitors.

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