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Summary

EFFICACY AND SAFETY OF OBEFAZIMOD IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS: RESULTS FROM TWO, PHASE 3, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, 8-WEEK INDUCTION TRIALS (ABTECT-1 & 2)

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Two Phase 3 induction trials (ABTECT-1 and ABTECT-2) demonstrated that obefazimod 50 mg once daily achieved statistically significant clinical remission at week 8 in patients with moderate-to-severe ulcerative colitis, including those with multiple prior therapy failures.

KEY POINTS

- In ABTECT-1, obefazimod 50 mg achieved 21.7% clinical remission versus 2.5% placebo (difference 19.3%, p<0.0001); in ABTECT-2, 19.8% versus 6.3% placebo (difference 13.4%, p=0.0001).
- Obefazimod 50 mg met all key secondary endpoints in both trials, including clinical response (61.0-63.2%), endoscopic improvement (33.3-35.5%), and histo-endoscopic mucosal improvement (23.0-23.9%).
- The 25 mg dose met the primary endpoint and all secondary endpoints in ABTECT-1 but did not meet the primary endpoint in ABTECT-2 (11.3% vs 6.3% placebo, p=0.1034).
- The most common adverse event was headache (20.8-25.8% with 50 mg, 14.5-15.6% with 25 mg, 5.7% placebo), which was mild, transient, and led to discontinuation in only 0-1.6% of patients.
- No signal was observed for serious, severe, or opportunistic infections or malignancies; overall serious adverse events and discontinuation rates were similar to placebo.
- Study population included 45.3-49.3% with inadequate response to one or more advanced therapies, with no upper limit on prior treatment failures.

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