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Summary

LONG-TERM EFFICACY AND PERSISTENCE WITH OBEFAZIMOD AFTER DOSE DE-ESCALATION TO 25 MG: 3-YEAR INTERIM ANALYSIS IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS COMPLETING WEEK 144, STRATIFIED BY PRIOR ADVANCED THERAPY EXPERIENCE: RESULTS F

Bram Verstockt

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Obefazimod 25mg once daily maintained high rates of clinical remission (85%), symptomatic remission (88–90%), and endoscopic improvement (92%) through three years after dose reduction from 50mg in ulcerative colitis patients who had completed Phase 2 open-label studies.

KEY POINTS

- Among 104 patients completing week 144, clinical remission was sustained at 84.6%, symptomatic remission at 90.4%, endoscopic improvement at 92.3%, and endoscopic remission at 72.1%.
- Patients received Obefazimod 50mg once daily for 2–4 years in prior Phase 2 open-label maintenance studies before dose reduction to 25mg once daily for an additional three years.
- In the subgroup with prior inadequate response to advanced therapies (45.2% of completers), clinical remission ranged from 77% to 79% and symptomatic remission from 83% to 85% at weeks 48 through 144.
- Patients without prior advanced therapy exposure showed numerically higher efficacy rates across all endpoints, particularly for endoscopic remission.
- Obefazimod is an oral, once-daily small molecule that enhances microRNA-124 expression, restoring mucosal immune balance through regulation of Th17 cells and macrophages.
- The analysis included only patients who completed the week 144 visit (as-observed analysis) after 130 patients enrolled in the open-label extension from 174 prior study completers.

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