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Summary

OBEFAZIMOD IN PATIENTS WITH MODERATE-TO-SEVERE ULCERATIVE COLITIS: EFFICACY AND SAFETY ANALYSIS FROM THE 96-WEEK OPEN-LABEL MAINTENANCE PHASE 2B STUDY

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Endoscopy | Histopathology | IBD

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Obefazimod 50mg once daily demonstrated sustained efficacy and safety over 96 weeks of open-label maintenance in moderate-to-severe ulcerative colitis, with 52.5% of patients achieving clinical remission.

KEY POINTS

- At week 96, clinical remission was achieved by 52.5% of patients, endoscopic improvement by 59.0%, and endoscopic remission by 35.9%.
- Among 168 patients without clinical remission after induction, 48.2% achieved de novo clinical remission at week 96; among 49 with induction remission, 67.3% maintained remission at week 96.
- Treatment emergent adverse events led to discontinuation in 7.8% of patients; serious adverse events occurred in 8.3%; no new safety risks were identified over 96 weeks.
- Most frequent adverse events (≥5%) were COVID-19 (14.3%), headache (11.5%), ulcerative colitis (7.8%), and nasopharyngitis (6.9%).
- Half of patients were previously exposed to biologics or JAK inhibitors; 60% received concomitant corticosteroids during induction.
- Obefazimod is an oral small molecule that modulates inflammation by upregulating microRNA-124.

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