EFFICACY AND SAFETY OF DUVAKITUG MAINTENANCE THERAPY IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS (UC): RESULTS FROM THE PHASE 2B RELIEVE UCCD LONG-TERM EXTENSION STUDY

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Duvakitug maintenance therapy (450 mg or 900 mg subcutaneous every 4 weeks) achieved clinical remission in 47% and 58% of patients, respectively, at week 44 in moderately to severely active ulcerative colitis patients who responded to induction therapy in the phase 2b RELIEVE UCCD long-term extension study.

KEY POINTS

- At week 44 of maintenance (58 weeks total exposure), clinical remission was achieved by 47% of patients receiving duvakitug 450 mg every 4 weeks (95% CI: 30, 65) and 58% receiving 900 mg every 4 weeks (95% CI: 42, 73).
- Clinical response was achieved in 82% (450 mg) and 87% (900 mg) of patients, and endoscopic improvement in 59% (450 mg) and 63% (900 mg) of patients at week 44.
- Treatment-emergent adverse events occurred in 59% (450 mg) and 67% (900 mg) of patients, were mostly mild to moderate in severity, and most commonly consisted of upper respiratory tract infection; adverse events leading to discontinuation occurred in 4% (450 mg) and 2% (900 mg) of patients.
- Duvakitug appeared to demonstrate a dose response, and no new safety concerns were identified during the 44-week maintenance phase.
- The study supports duvakitug as a potentially effective and durable maintenance treatment for ulcerative colitis and is being further evaluated in phase 3 trials; duvakitug is an anti-TL1A monoclonal antibody developed in partnership by Teva and Sanofi.

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