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Summary

EFFICACY AND SAFETY OF HALF-LIFE EXTENDED ANTIBODIES SPY001, SPY002, AND SPY003 FOR INDUCTION TREATMENT OF MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS

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Mechanisms & Personalised Medicine | Immunology | IBD

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SKYLINE-UC Part A open-label induction data showed SPY001 (anti-α4β7), SPY002 (anti-TL1A), and SPY003 (anti-IL-23) each met the primary endpoint of statistically significant reduction in Robarts Histopathology Index at Week 12 in moderately to severely active ulcerative colitis.

KEY POINTS

- SPY001 reduced RHI by -9.2 points (95% CI: -12.6, -5.7, p<0.0001) with 39.5% achieving clinical remission and 51.2% achieving endoscopic improvement at Week 12.
- SPY002 reduced RHI by -10.7 points (95% CI: -14.1, -7.2, p<0.0001) with 33.3% achieving clinical remission and 41.7% achieving endoscopic improvement at Week 12.
- SPY003 data were available at presentation showing statistically significant RHI reduction with 20% clinical remission and 30% endoscopic improvement at Week 12.
- All three antibodies reduced modified Mayo Score by approximately 3.5 to 3.7 points from baseline (p<0.0001 for SPY001 and SPY002).
- Safety profiles were consistent with known α4β7, TL1A, and IL-23 antibody classes with no deaths; 14.0% of SPY001 and 41.7% of SPY002 participants reported treatment-emergent adverse events.
- The antibodies have half-life extending modifications designed to enable quarterly or semiannual dosing; Part B of the trial is evaluating these agents and their pairwise combinations in a placebo-controlled factorial design.

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