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Summary

EFFICACY AND SAFETY OF THE FIRST CO-ANTIBODY THERAPY, JNJ-78934804, IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS REFRACTORY TO TWO OR MORE SYSTEMIC THERAPY MECHANISMS

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JNJ-78934804, the first fixed-dose co-antibody therapy combining guselkumab and golimumab, demonstrated substantial efficacy in ulcerative colitis patients refractory to two or more prior systemic therapies, with week 48 clinical remission of 26.7% versus 2.1% for golimumab and 16.0% for guselkumab monotherapies.

KEY POINTS

- In the Phase 2b DUET-UC study subpopulation with UC refractory to two or more systemic therapy mechanisms, high-dose JNJ-4804 achieved week 48 clinical remission in 26.7% versus 4.8% placebo, with adjusted differences of 22.9% versus golimumab and 12.5% versus guselkumab.
- Week 48 endoscopic improvement was 35.6% with high-dose JNJ-4804 versus 2.1% golimumab (adjusted difference 31.9%) and 20.0% guselkumab (adjusted difference 17.3%).
- The composite endpoint of histologic remission and endoscopic improvement at week 48 was achieved by 31.1% on high-dose JNJ-4804 versus 2.1% golimumab (adjusted difference 27.3%) and 16.0% guselkumab (adjusted difference 16.9%).
- Corticosteroid-free clinical remission at week 48 was 24.4% with high-dose JNJ-4804 versus 2.1% golimumab (adjusted difference 20.5%) and 14.0% guselkumab (adjusted difference 12.3%).
- The safety profile of JNJ-4804 was similar to the monotherapies, with no deaths, low serious infection rates (8.9 per 100 patient-years for high dose), and adverse event discontinuation rates of 8.9 per 100 patient-years.

– JNJ-4804 targets the complementary IL-23 and TNF pathways and is the first co-antibody therapy in development for inflammatory bowel disease; results support advancement to Phase 3.

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