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Summary

DEVELOPMENT AND CHARACTERIZATION OF SIM0709, A NOVEL HALF-LIFE EXTENDED BI-SPECIFIC ANTIBODY SIMULTANEOUSLY TARGETING TL1A AND IL-23P19 FOR THE TREATMENT OF IBD AND BEYOND

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SIM0709, a bi-specific antibody targeting both TL1A and IL-23p19, demonstrated superior dual pathway blockade and extended half-life in preclinical models of inflammatory bowel disease with a first-in-human study expected in H1 2026.

KEY POINTS

- SIM0709 bound to both TL1A and IL-23 proteins with sub-nanomolar affinity and showed superior functional activities on both axes compared to benchmark anti-TL1A mAb RG6631 and Guselkumab or its combination.
- In a cytokine-induced acute gut inflammation model, SIM0709 exhibited superior dual pathway blockade synergy with significantly reduced inflammatory cytokines/chemokine levels and improved histological scores compared to either anti-TL1A or anti-IL-23p19 monotherapies.
- SIM0709 demonstrated an improved serum half-life in human FcRn knock-in mice compared to RG6631, with over 15 days half-life observed in non-human primates.
- The authors are employees of Jiangsu Simcere Pharmaceutical Co., Ltd and State Key Laboratory of Neurology and Oncology Drug Development.

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