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Summary

DEVELOPMENT AND CHARACTERIZATION OF SPY003, A NOVEL EXTENDED HALF-LIFE MONOCLONAL ANTIBODY DRUG CANDIDATE TARGETING IL-23 FOR THE TREATMENT OF IBD

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SPY003, a novel extended half-life monoclonal antibody targeting IL-23, demonstrates picomolar binding affinity and potent inhibition of IL-23 signaling comparable to existing therapies, with potential for twice-yearly dosing in inflammatory bowel disease.

KEY POINTS

- SPY003 binds IL-23 with picomolar affinity and inhibits STAT3 activity with IC50 values less than 1nM, comparable to risankizumab and guselkumab
- The antibody demonstrates significantly extended half-life in cynomolgus monkeys compared to both risankizumab and guselkumab
- Predictive simulations based on allometric scaling suggest Q3M-Q6M+ subcutaneous dosing may achieve therapeutic exposures across a wide range of patient body weights and albumin concentrations
- SPY003 inhibits IL-17 secretion in IL-23-stimulated mouse splenocytes and human peripheral blood mononuclear cells
- The authors conclude SPY003 demonstrates therapeutic potential for Crohn's disease and ulcerative colitis with the potential advantage of twice-yearly subcutaneous dosing, though further clinical studies are needed

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