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Summary

BBT003, A NOVEL IL-23P19 X TL1A BISPECIFIC ANTIBODY WITH EXTENDED HALF-LIFE, DEMONSTRATES A POTENTIAL BEST-IN-DISEASE PROFILE IN PRECLINICAL MODELS OF INFLAMMATORY BOWEL DISEASE

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BBT003, a bispecific antibody co-targeting IL-23 and TL1A with Fc engineering for half-life extension, demonstrated superior anti-inflammatory and anti-fibrotic efficacy over single-targeting monoclonal antibodies in preclinical IBD models.

KEY POINTS

- BBT003 outperformed single-targeting monoclonal antibodies including guselkumab and tulisokibart analogues in a TNBS-induced colitis mouse model, with statistically significant dose-dependent reductions in disease activity index, colon histopathology, inflammation, and fibrosis while restoring body weights.
- The bispecific antibody demonstrated simultaneous dual-target binding and blockade, resulting in enhanced suppression of IL-17A release from mouse splenic lymphocytes co-stimulated with IL-23 and TL1A compared with single-targeting antibodies.
- BBT003 selectively inhibited TL1A interaction with DR3 while sparing binding to the decoy receptor DcR3, a profile not observed with tulisokibart or afimkibart analogues and more pronounced than duvakitug analogue, potentially preserving endogenous regulatory control.
- The molecule completely inhibited IL-23-induced STAT3 signaling and IL-17A expression, as well as TL1A-induced NF-κB signaling, TF-1 cell apoptosis, and IFN-γ expression in cell-based assays.
- In cynomolgus monkeys, BBT003 was well tolerated at the highest tested dose under repeat-dose conditions, providing a wide safety margin to support clinical development.

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