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Summary

EVALUATION OF CHANGES IN GENE EXPRESSION IN COLONIC BIOPSY SAMPLES FROM PATIENTS TREATED WITH AFIMKIBART IN THE TUSCANY-2 TRIAL

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Single-cell RNA sequencing analysis of colonic biopsies from the TUSCANY-2 trial demonstrates that afimkibart, an anti-TL1A antibody, induced complete target inhibition and broad transcriptomic changes across immune and tissue-resident cells in patients with moderately to severely active ulcerative colitis.

KEY POINTS

- A TL1A-responsive CD4 T-cell gene expression signature was significantly inhibited in CD4 T-cells from screening to week 14 with afimkibart 450 mg treatment (p=0.0000252), but not with placebo, confirming target engagement.
- Afimkibart-treated patients showed broad transcriptomic changes across epithelial, myeloid, fibroblast, and T-cell lineages, whereas very few changes were observed in the placebo group.
- Pathway analysis within CD4 T-cells showed decreases in cellular division post-treatment, consistent with reductions in T-cell lineage abundance at week 14.
- The mode of action extends beyond suppression of inflammation to modulation of dysregulated epithelial and stromal/fibrotic tissue programmes, affecting cell types without prominent DR3 expression.
- This is the first interventional trial in this class to assess TL1A blockade at single-cell resolution in colonic tissue.

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