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Summary

PHARMACOKINETICS OF RECTALLY ADMINISTERED COBITOLIMOD IN PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS: A PHASE IB OPEN-LABEL STUDY

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A phase Ib study in eight patients with moderate to severe ulcerative colitis found that rectally administered cobitolimod (500 mg) resulted in low systemic exposure with short plasma half-life and was well tolerated with no serious adverse events.

KEY POINTS

- Rectal administration of 500 mg cobitolimod at week 0 in seven patients yielded median Cmax of 21.7 ng/ml, median Tmax of 1 hour, median AUC0-last of 71.7 h*ng/ml, and T1/2 less than 2.5 hours.
- Four of seven patients achieved clinical remission at week 6, defined by 3-component Mayo score with no rectal bleeding, stool frequency subscore ≤1 with ≥1 point decrease from baseline, and endoscopic subscore ≤1.
- In the four patients achieving remission at week 6, median Cmax was 15.5 ng/ml and median AUC0-last was 27.6 h*ng/ml, with Tmax of 0.5 hours and T1/2 remaining less than 2.5 hours.
- Twenty-four adverse events occurred, the majority mild and judged unlikely related to study drug, with no serious adverse events reported.
- This open-label single-center study supports that cobitolimod, a Toll-like receptor 9 agonist in phase III development for left-sided ulcerative colitis, demonstrates limited systemic absorption both in active disease and clinical remission.

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