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Summary

EFFECT OF MILD OR MODERATE HEPATIC IMPAIRMENT ON THE PHARMACOKINETICS OF OZANIMOD

Daniel Tatosian

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A phase 1 study (NCT04639115) found that mild or moderate hepatic impairment did not meaningfully alter ozanimod pharmacokinetics during dose titration but led to approximately 2-fold increases in exposure to its two major active metabolites, leading to a recommendation for alternate-day dosing after titration in this population.

KEY POINTS

- The study enrolled 26 participants (8 mild hepatic impairment, 8 moderate hepatic impairment, 10 matched healthy controls) who received ozanimod with dose titration from 0.23 mg to 0.92 mg over 8 days.
- No clinically meaningful differences in ozanimod or metabolite pharmacokinetics were observed between hepatic-impaired and healthy participants during the dose titration period (Days 1, 5, and 8).
- Unbound AUC_{0-last} for both major active metabolites (CC112273 and CC1084037) increased approximately 2-fold in participants with mild or moderate hepatic impairment compared to matched healthy controls.
- No treatment-emergent adverse events were reported for laboratory results, vital signs, physical examination, or ECG findings.
- Based on these findings, the authors recommend ozanimod 0.92 mg once every other day in patients with mild or moderate hepatic impairment after completing the standard 1-week dose titration.

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