FDA Clears Path to Clinic Without Additional IND-Enabling Toxicology studies

FDA removes key barrier, accelerating IND and clinical entry for Cethromycin HCl in liver-stage malaria

BALTIMORE, MD, UNITED STATES, April 13, 2026 /EINPresswire.com/ -- AliquantumRx Inc. today announced positive regulatory feedback from its Type B pre-Investigational New Drug (pre-IND) meeting with the U.S. Food and Drug Administration (FDA) regarding the development of cethromycin hydrochloride (cethromycin HCl) for liver-stage malaria.

Based on extensive prior human exposure to cethromycin base, FDA indicated that additional nonclinical toxicology studies are not recommended at this time to support initiation of Phase I clinical studies with cethromycin hydrochloride. This guidance enables a streamlined path into the clinic and removes a major preclinical gating step. The Agency noted that nonclinical IND-enabling studies with cethromycin HCl will still be required to support a future New Drug Application.

AliquantumRx can now advance toward IND submission with a primary focus on Chemistry, Manufacturing and Controls (CMC) and clinical protocol development, significantly reducing development timelines while accelerating the transition to human pharmacokinetic and safety evaluation.

“This is an important moment for the program,” said Nikola Kaludov, PhD, President and Co-Founder of AliquantumRx. “FDA is comfortable with the totality of cethromycin’s pre-clinical data to move directly into clinical development to acquire human pharmacokinetics, safety and proof-of-biology.”

FDA feedback also indicated alignment with the Company’s broader development strategy. The proposed early clinical drug product approach, including CGMP API just-in-time capsule filling, was considered appropriate for Phase I, and the overall clinical framework was viewed as acceptable, with additional input expected at IND submission.

AliquantumRx plans to submit an IND in Q3/Q4 2026 and initiate a Phase I study to characterize pharmacokinetics, safety, and hepatic exposure—data that will inform a controlled human malaria infection (CHMI) study designed to establish early proof-of-biology in liver-stage malaria.

Cethromycin HCl is being developed as a short-course, exposure-driven therapy targeting dormant liver-stage malaria parasites responsible for relapse. The program builds on extensive prior human safety experience with cethromycin base and a pharmacologic profile designed to achieve high intracellular and hepatic exposure, enabling a capital-efficient path to clinical proof-of-concept.

About AliquantumRx Inc.
AliquantumRx is a near-clinical infectious-disease company developing Cethromycin HCl, a glucose-6-phosphate dehydrogenase (G6PD) test-independent, short-course therapy designed to eliminate dormant liver-stage malaria and prevent relapse.

Cautionary Note Regarding Forward-Looking Statements
Except for historical information, the matters set forth above may be forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially, including regulatory outcomes and clinical development timelines. AliquantumRx undertakes no obligation to update such statements.

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