Jaguar Health Family Company Napo Pharmaceuticals Successfully Completes Manufacture of Process Validation Batches of Lyophilized Crofelemer Formulation, a Critical Component of its Planned FDA Submission of a New Drug Application (NDA) for MVID in Mid-2027

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Company remains sharply focused on its ongoing rare disease intestinal failure (IF) global development program for microvillus inclusion disease (MVID) and short bowel syndrome (SBS-IF) for the novel lyophilized crofelemer powder for oral solution

SAN FRANCISCO, CA / ACCESS Newswire / November 24, 2026 / Jaguar Health, Inc. (Nasdaq:JAGX) family company Napo Pharmaceuticals (Napo) today announced that it has successfully completed the production of process validation (PV) batches of the lyophilized formulation of crofelemer powder for oral solution, and initiation of stability testing of these PV batches. This successful manufacture of process validation batches represents a critical milestone in support of the CMC (Chemistry, Manufacturing and Controls) component of the company's planned submission of the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in mid-2027 for the lyophilized formulation of crofelemer for the treatment of microvillus inclusion disease (MVID), an ultrarare pediatric intestinal failure disorder, and future regulatory submissions for SBS-IF.

CMC is one of three core sections of an NDA submission, alongside nonclinical safety and toxicology studies, and comprehensive clinical data. The CMC component provides critical information regarding consistency and quality of a new drug's manufacturing process, and the reproducibility of its purity, content uniformity and stability. Inadequate or unresolved manufacturing, testing and/or quality issues can result in significant delays in NDA review and approval.

"The chemistry, manufacturing and controls for the crofelemer drug substance were first approved by the FDA in 2012 during its review for the approval of crofelemer delayed-release tablets, a fixed dose formulation, for crofelemer's initial indication for the relief of HIV-associated diarrhea," said David Sesin, PhD, Napo's Chief Manufacturing Officer.

"Our successful manufacture of process validation batches for the novel lyophilized crofelemer powder for oral solution represents an important milestone in our IF development program as it supports the consistency and reproducibility of our manufacturing, testing and release processes for the lyophilized crofelemer formulation, which has been developed for personalized dosing of MVID and SBS-IF patients that are dependent on parenteral support to support Napo's planned NDA submission in mid-2027," said Mark Johnson, PhD, Napo's Senior Vice President of Pharmaceutical Development.

Patients with intestinal failure, including pediatric MVID patients and pediatric and adult patients with SBS-IF, cannot adequately orally absorb nutrients, electrolytes and fluids, and require lifelong supportive therapy with total parenteral nutrition (TPN) with or without supplemental intravenous fluids, which together comprises parenteral support (PS), for up to seven days per week and up to 20+ hours per day. While PS is supportive and lifesaving, it is associated with serious, sometimes fatal complications.

Napo remains sharply focused on its ongoing global development program for oral crofelemer as adjunctive therapy to PS for rare intestinal failure diseases, including MVID and SBS-IF. In June 2026, as announced, data was presented at the 58th Annual European Society for Pediatric Gastroenterology, Hepatology & Nutrition (ESPGHAN) Meeting in Lille, France from ongoing investigational studies with oral liquid crofelemer in pediatric patients with intestinal failure due to MVID and SBS-IF. The results of ongoing investigations of liquid oral crofelemer formulations demonstrate substantial reductions in weekly PS needs as well as in PS normalized to body weight in pediatric intestinal failure patients dosed orally for more than one year, with no significant clinical or laboratory abnormalities.

About the Jaguar Health Family of Companies

Jaguar Health, Inc. (Jaguar) is a commercial stage pharmaceuticals company focused on developing novel proprietary prescription medicines sustainably derived from plants from rainforest areas for people and animals with gastrointestinal distress. Jaguar family companies Napo Pharmaceuticals, Inc. (Napo) and Napo Therapeutics S.p.A. focus on the development and commercialization of novel crofelemer powder for oral solution for the treatment of rare and orphan gastrointestinal disorders with intestinal failure, including microvillus inclusion disease and short bowel syndrome.

For more information about:

Jaguar Health, visit https://jaguar.health

Napo Pharmaceuticals, visit napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that the company will file an NDA for crofelemer for MVID in mid-2027 and will conduct future regulatory submissions for SBS-IF. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this release are only predictions. Jaguar has based these forward-looking statements largely on its current expectations and projections about future events. These forward-looking statements speak only as of the date of this release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Jaguar's control. Except as required by applicable law, Jaguar does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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