



All Randomized Pediatric Patients to Continue in the Single-Blind Extension Phase of Jaguar Health's Pivotal Clinical Trial of Crofelemer for Microvillus Inclusion Disease (MVID) with Intestinal Failure (IF)

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SAN FRANCISCO, CA / [ACCESS Newswire](#) / September 10, 2026 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) (Jaguar) family company [Napo Pharmaceuticals](#) (Napo) today announced that all randomized pediatric MVID patients in Napo's pivotal crossover clinical trial have entered the single-blind extension phase to receive blinded doses of crofelemer to support longer-term safety and efficacy for crofelemer powder for oral solution as adjunctive therapy to parenteral support (PS). The trial is ongoing at multiple centers in the United States, the European Union, and the United Arab Emirates. This trial is expected to support a New Drug Application (NDA) filing for the treatment of the MVID indication in mid-2027.

Patients with intestinal failure (IF), including those with MVID or short bowel syndrome (SBS), cannot orally absorb adequate nutrients, electrolytes and fluids, and require lifelong total parenteral nutrition (TPN) with or without supplemental intravenous fluids, which together comprise PS, for up to seven days per week and up to 20+ hours per day. While PS is supportive, palliative 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 pediatric rare IF diseases, including MVID and short bowel syndrome with IF (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 IF 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 IF patients dosed orally for more than one year, with no significant clinical or laboratory abnormalities. In one MVID patient, the weekly PS requirements normalized to body weight have been reduced by up to 48% following >12 months of liquid oral high-dose crofelemer therapy. In two pediatric SBS-IF patients, weekly PS requirements normalized to body weight were reduced up to 40% following >12 months of liquid oral high dose crofelemer therapy.

"We are pleased that all randomized pediatric MVID patients will participate in the single-blind extension phase with blinded doses of crofelemer powder for oral solution. An independent Data Monitoring Committee evaluated the safety and tolerability of crofelemer during the randomized double-blind crossover period of the trial and authorized continuation of active crofelemer treatment for a longer period in the extension phase," said Pravin Chaturvedi, PhD, Napo's and Jaguar's Chief Scientific Officer and Chair of the Scientific Advisory Board. "As previously reported at ESPGHAN 2026, long-term crofelemer treatment has been well tolerated and demonstrated significant reductions in PS normalized to body weight in two open-label investigations in pediatric MVID patients."

"Our IF program is expected to continue to provide clinical milestones, including an NDA filing for MVID and the completion of a Phase 2 study in SBS-IF by mid-2027. The totality of our IF program with the same powder for liquid crofelemer formulation is the subject of business development discussions with the potential to bring in non-dilutive funds from potential licensee partners," said Lisa Conte, Jaguar's founder, president, and CEO. "Upon completion of the trial, data from this study may serve as the basis for a [Breakthrough Therapy Designation](#) application. Because MVID is a devastating ultrarare pediatric disorder with a lethal natural history - and an estimated worldwide prevalence of only 200 patients - a trial of crofelemer in just a small number of MVID patients is expected to be clinically meaningful and significant."

About Crofelemer

Crofelemer is a novel, oral plant-based prescription medicine purified from the red bark sap, also referred to as "dragon's blood," of the *Croton lechleri* tree in the Amazon Rainforest. Napo Pharmaceuticals has established a sustainable harvesting program, under fair trade practices, for crofelemer to ensure a high degree of quality, ecological integrity, and support for indigenous communities.

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 its intestinal failure program will continue to provide clinical milestones, including an NDA filing for MVID and the completion of a Phase 2 study in SBS-IF by mid-2027, Jaguar's expectation that the opportunity may exist to bring in non-dilutive funds from potential licensee partners to support the intestinal failure program, Jaguar's plans to pursue Breakthrough Therapy Designation for crofelemer for the indication of MVID, and Jaguar's expectation that a trial of crofelemer in a small number of MVID patients may be clinically meaningful and significant. 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 several 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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