# In Support of Possible Expedited Approval Pathway for Crofelemer for Treatment of Microvillus Inclusion Disease (MVID), Jaguar Health Submits Amended Protocol to FDA for Ongoing Placebo-Controlled Clinical Trial

November 20, 2025

***Crofelemer can potentially extend lives of MVID patients - infants and children who face the lethal natural history of the disease***

***Parenteral support reduction of up to 37% is groundbreaking; No approved treatments exist for MVID in any region***

**SAN FRANCISCO, CALIFORNIA / ACCESS Newswire / November 20, 2025 /** Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar) family company Napo Pharmaceuticals (Napo) today announced that, in support of a possible expedited approval pathway for crofelemer for treatment of intestinal failure in patients with the ultrarare genetic disorder microvillus inclusion disease (MVID), the company has submitted an amended protocol to the U.S. Food and Drug Administration (FDA) for the company's ongoing placebo-controlled clinical trial of crofelemer in pediatric MVID patients.

MVID patients are born without the ability to absorb the basic nutrients of life, and are therefore subject to a lethal natural history and a lifetime of parenteral support which is associated with toxicities and comorbidities. The ability of crofelemer to decrease the volume of parenteral support is potentially life extending for these patients and is thus disease progression modifying. Crofelemer provides an opportunity for improved quality of life, potentially reducing the time MVID patients spend on parenteral nutrition and/or supplemental intravenous fluids by up to 37% a day from what is often up to 20 hours a day, 7 days a week to support the daily electrolyte and nutrient needs of the patient.

"In light of the initial groundbreaking results of the investigator-initiated trial (IIT) of crofelemer in the United Arab Emirates for treatment of MVID and in support of our efforts to make crofelemer available to children with MVID as quickly and efficiently as possible, as announced, the company met with the FDA on October 2, 2025 to seek their advice regarding our ongoing clinical trial of crofelemer for MVID treatment. Based on the feedback from the FDA during this meeting, we have proposed an amendment to our protocol for this study and submitted the amended protocol to the FDA for their review. Our expectation is that the amended protocol, along with the results of this study, if positive, will support a faster FDA review and approval of crofelemer for MVID," said Pravin Chaturvedi, PhD, Jaguar's Chief Scientific Officer and Chair of the Jaguar and Napo Scientific Advisory Board.

Jaguar has also discussed the potential for approval of crofelemer for MVID with the European Medicines Agency, the EU's equivalent of the FDA, based on a study in potentially a small number of patients given the burden of MVID. "That's how unprecedented crofelemer's mechanism of action and these results are in intestinal failure patients with MVID," said Lisa Conte, Jaguar's founder, president, and CEO. "MVID is a devastating ultrarare pediatric disorder, with an estimated worldwide prevalence of only 100-200 patients, so a trial of crofelemer in just a small number of MVID patients is expected to be statistically meaningful."

As presented on November 8, 2025, at the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) Annual Meeting, the initial groundbreaking results of an ongoing and independent IIT of crofelemer in the UAE for treatment of pediatric intestinal failure, which includes patients with intestinal failure due to MVID and short bowel syndrome (SBS-IF), demonstrate disease progression modification through reduction of total parenteral support (PS) in pediatric intestinal failure patients that ranged from 12 to 37%. For the initial MVID patient who has completed treatment, PS needs were reduced by up to 27% at the highest dose over the initial 12-week treatment period and up to 37% during the extension period upon reinitiation of crofelemer treatment, and also showed reduced frequency of loose watery stools. This finding supports continued evaluation of crofelemer to reduce PS needs for pediatric MVID patients.

MVID causes intestinal failure, a situation where the patient's intestines are unable to absorb the fluids, electrolytes and nutrients required to survive and thrive. Intestinal failure is a debilitating, morbid and lifelong condition that often requires patients to receive life-sustaining fluids, electrolytes and nutrients through intravenous administration, which consists of total parenteral nutrition (TPN) with supplemental intravenous fluids, which together constitute parenteral support (PS). Most intestinal failure patients require PS up to 7 days a week, and sometimes for 20 hours or more per day. While crucial for these patients, PS is associated with significant toxicities to patients, similar to some toxicities associated with chemotherapy, often causing serious health problems including infections, metabolic complications, liver and kidney function problems - as well as a risk of neurodevelopmental delay. These symptoms may emerge at any time in intestinal failure patients, and often become life-threatening.

In addition to supporting the IIT in the UAE and conducting the placebo-controlled clinical trial of crofelemer in pediatric MVID patients at sites in the U.S., E.U., and Middle East, the company is also providing crofelemer powder for oral solution for use in two expanded access programs in the U.S. to treat intestinal failure in pediatric patients with MVID.

**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 (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 MVID and short bowel syndrome.

For more information about:

Jaguar Health, visit https://jaguar.health

Napo Pharmaceuticals, visit www.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 amended protocol the company submitted to the FDA for the company's ongoing trial of crofelemer for the treatment of intestinal failure in MVID patients will support a possible expedited approval pathway for crofelemer for this indication, Jaguar's expectation that the ability of crofelemer to decrease the volume of PS is life extending and disease progression modifying for MVID patients, and that crofelemer provides an opportunity for improved quality of life for MVID patients by reducing the time MVID patients spend on parenteral nutrition and/or supplemental intravenous fluids by up to 37% a day, Jaguar's expectation that the amended protocol, along with the results of the company's study, if positive, will support a faster FDA review and approval of crofelemer for treatment of MVID, and Jaguar's expectation that crofelemer could also be approved by the European Medicines Agency for MVID based on a study in potentially a small number of patients. 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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