



## **FDA Feedback Supports Extension Phase for Jaguar Health's Clinical Trial of Crofelemer for Treatment of Microvillus Inclusion Disease (MVID)**

March 18, 2026

***MVID has a lethal natural history requiring life-sustaining parenteral support (PS), which includes total parenteral nutrition (TPN), which is associated with significant toxicities; PS reduction could potentially reduce co-morbidities and improve clinical benefit, as no approved therapies exist for MVID***

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**SAN FRANCISCO, CA / [ACCESS Newswire](#) / March 18, 2026 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#)** (Jaguar) family company Napo Pharmaceuticals (Napo) today announced that, based on the U.S. Food and Drug Administration (FDA) support for Napo's protocol amendment for its clinical trial to evaluate the safety and efficacy of its novel crofelemer powder-for-oral-solution formulation in pediatric patients with intestinal failure due to MVID, an ultrarare pediatric disorder, Napo plans to initiate a single-blind extension phase for the trial. The extended treatment period has the potential to improve clinical benefit of crofelemer through reduction of parenteral support (PS) requirements, which may result in disease progression-modification of MVID.

"We are pleased to have the opportunity to continue treatment with crofelemer powder for oral solution in our ongoing clinical trial of crofelemer in pediatric MVID patients," said Pravin Chaturvedi, PhD, Jaguar's Chief Scientific Officer and Chair of the Jaguar and Napo Scientific Advisory Board. "This would allow patients who have completed their double-blind treatment period to be eligible for the single-blind phase of continued treatment with crofelemer for further assessment of clinical benefit through reduction of PS for a longer period. PS reduction could potentially reduce co-morbidities associated with the disease and TPN; thus improving clinical benefit and modifying the disease progression to help address the lethal natural history of MVID."

The dose selection for the single-blind extension phase will be determined by the study's independent Data Monitoring Committee (DMC), which will ensure that the study clinicians and Napo personnel will remain blinded. Currently, approximately 30% of the participating MVID patients have completed the study's double-blind treatment phase and the clinical investigators are supporting the patients' participation in the single-blind extended phase.

This trial of crofelemer in MVID patients has clinical sites in the US, Italy and the UAE, and the consent from the FDA, the European Medicines Agency (EMA), The Ministry of Health and Prevention (MOHAP), and the Institutional Review Boards (IRBs) for each site.

"Our development plan for this ultrarare disease, with an expected improved clinical benefit from the longer treatment in the extension phase, may also support the possibility for a [Breakthrough Therapy](#) designation from the FDA in the coming months, potentially supporting opportunities for expedited regulatory submission pathways to the FDA for new drug approval for this ultrarare pediatric disorder," said Lisa Conte, Jaguar's founder, president, and CEO. "The extremely low incidence and prevalence of MVID, its lethal natural history and the fact that no therapies are available for MVID other than lifelong PS, underscores the need for new therapies. Together with the support of MVID clinical key opinion leaders (KOLs), we are exploring expedited regulatory pathways for crofelemer."

### **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](http://www.napopharma.com)

Napo Therapeutics, visit [napotherapeutics.com](http://napotherapeutics.com)

### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that Napo

will initiate a single-blind extension phase for its MVID trial, the expectation that PS reduction could potentially reduce co-morbidities associated with MVID and TPN, thus improving clinical benefit and modifying the disease progression to help address the lethal natural history of MVID, and Jaguar's expectation that its development plan for MVID may support the possibility for a Breakthrough Therapy designation from the FDA in the coming months, potentially supporting opportunities for expedited regulatory submission pathways to the FDA for new drug approval. 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.

**Contact:**

[hello@jaguar.health](mailto:hello@jaguar.health)

Jaguar-JAGX

**SOURCE:** Jaguar Health, Inc.

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