



Jaguar Health Family Company Napo Pharmaceuticals to Meet with FDA to Discuss Potential Regulatory Pathways for Crofelemer for Treatment of Ultrarare Pediatric Indication Microvillus Inclusion Disease (MVID)

August 19, 2025

As [announced](#), initial proof-of-concept results from the ongoing investigator-initiated trial in Abu Dhabi show crofelemer reduced the required total parenteral nutrition in the first participating MVID patient by up to 27%; abstract describing results accepted for presentation at upcoming [North American Society for Pediatric Gastroenterology, Hepatology and Nutrition \(NASPGHAN\) 2025 Annual Meeting in Chicago](#)

SAN FRANCISCO, CA / [ACCESS Newswire](#) / August 19, 2025 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) (Jaguar) family company [Napo Pharmaceuticals](#) (Napo) today announced that it plans to meet with the U.S. Food and Drug Administration (FDA) to discuss the company's ongoing clinical development program for crofelemer for the treatment of microvillus inclusion disease (MVID), an ultrarare pediatric disorder. Members of Napo's Scientific Advisory Board will join Napo and Jaguar representatives at the meeting.

"We're very pleased that Napo has been granted a meeting with the FDA to discuss Napo's development plans for crofelemer for MVID - a devastating pediatric disease characterized by severe malabsorption that requires life-sustaining parenteral support to meet the nutritional, fluid and electrolyte requirements of the child, and for which there are no approved drug treatments," said Pravin Chaturvedi, PhD, Napo's and Jaguar's Chief Scientific Officer and Chair of the Scientific Advisory Board. "A core Napo goal for this meeting is to obtain input from the FDA on the clinical program and potential expedited regulatory pathways for this rare orphan indication."

As [announced](#), and as presented April 26, 2025 at the [Annual ELITE PED-GI Congress](#), the initial proof-of-concept results of the ongoing investigator-initiated trial (IIT) of a novel crofelemer powder formulation for oral solution in Abu Dhabi in the United Arab Emirates show that crofelemer reduced the required total parenteral nutrition (TPN) and supplementary intravenous fluids in the first participating MVID patient by up to 27%. An abstract describing the initial results of this trial has been accepted for presentation at the upcoming [North American Society for Pediatric Gastroenterology, Hepatology and Nutrition \(NASPGHAN\) Annual Meeting](#) taking place November 5-8, 2025 in Chicago.

Jaguar, through Napo, is supporting the independent proof-of-concept IIT in pediatric intestinal failure (IF) patients at [Sheikh Khalifa Medical City](#) in Abu Dhabi, and is conducting the placebo-controlled Phase 2 study of crofelemer in pediatric MVID patients with IF at sites in the U.S., European Union, and Middle East/North Africa regions under appropriate regulatory approvals in each of these geographies.

"Given the ultrarare nature of MVID, and the groundbreaking initial proof-of-concept results from the IIT in Abu Dhabi, even a small number of MVID patients showing benefit with crofelemer may allow Napo to explore pathways for expedited regulatory approval," said Lisa Conte, Jaguar's Founder and CEO.

Based on the initial findings from the IIT in Abu Dhabi, crofelemer's paradigm-shifting mechanism of action has the potential to provide a novel therapeutic option to reduce parenteral support and associated complications in MVID patients.

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 Napo personnel will meet with the FDA to discuss Napo's development plans for crofelemer for MVID, statements regarding Jaguar's expectation that an

abstract describing the results of the investigator-initiated trial in Abu Dhabi will be presented at NASPGHAN 2025, Jaguar's expectation that even a small number of MVID patients showing benefit with crofelemer may allow Napo to explore pathways for expedited regulatory approval, and Jaguar's expectation that crofelemer's paradigm-shifting mechanism of action has the potential to provide a novel therapeutic option to reduce parenteral support and associated complications in MVID 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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