



Jaguar Health Provides Overview of 2025 Crofelemer-Related Catalysts

May 7, 2025

Crofelemer is the only oral drug approved by the FDA's Center for Drug Evaluation and Research under [Botanical Guidance](#)

Click [here](#) to access replay of company's April 30, 2025 investor webcast

SAN FRANCISCO, CA / [ACCESS Newswire](#) / May 7, 2025 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) (Jaguar) today provided an overview of expected Q2 - Q4 2025 catalysts related to potential follow-on indications for crofelemer, the company's novel plant-based prescription drug approved by the U.S. Food and Drug Administration's [Center for Drug Evaluation and Research](#) (CDER).

"As discussed during Jaguar's investor webcast last week, 2025 is a year of catalysts for crofelemer in both of our major development programs - our rare disease intestinal failure program and our cancer therapy-related diarrhea program," said Lisa Conte, Jaguar's Founder and CEO. "As a reminder, crofelemer is the only oral drug approved under the FDA's [Botanical Guidance](#). It is not a biologic product. Click [here](#) to access the replay of our April 30, 2025 investor webcast."

Rare Disease Intestinal Failure Program

Initial proof-of-concept (POC) results were issued last week for the ongoing investigator-initiated trial (IIT) of a novel liquid formulation of crofelemer in Abu Dhabi in the United Arab Emirates in pediatric patients with intestinal failure due to the rare orphan diseases microvillus inclusion disease (MVID) and short bowel syndrome (SBS-IF).

- The initial POC results, presented April 26, 2025 at the [Annual ELITE PED-GI Congress](#), show crofelemer reduced the required total parenteral nutrition (TPN) and/or supplementary intravenous fluids, collectively referred to as parenteral support, in patients with intestinal failure due to MVID and SBS-IF by up to 27% and 12.5% respectively
- Crofelemer also reduced stool volume output, frequency of watery stools, and increased urine output - indicating improved nutrient oral absorption
- Based on these initial findings, crofelemer's novel antisecretory mechanism of action appears to have the potential to provide a novel therapeutic option to reduce TPN and associated complications, including liver, renal, and cognitive deficits, as well as infections from IV infusion, in this patient population
- The observed TPN reduction is particularly compelling for MVID, an ultrarare pediatric disease characterized by severe diarrhea and malabsorption that requires intensive parenteral support for nutritional and fluid management and for which no approved drug treatments exist, or any potential approach to reduce TPN
- This initial proof-of-concept data in MVID supports crofelemer's potential inclusion in the European Medicines Agency's (EMA) [PRIME](#) program for expedited and assisted regulatory approval in the EU as well as in the FDA's [Breakthrough Therapy](#) program for expedited regulatory approval in the US
- Jaguar, through Jaguar family companies [Napo Pharmaceuticals](#) (Napo) and [Napo Therapeutics](#), is currently supporting three POC IITs, and conducting two placebo-controlled Phase 2 studies, for crofelemer for MVID and/or SBS-IF patients in the US, EU, and/or Middle East/North Africa regions
- Additional POC results from IITs in MVID and/or SBS-IF are expected throughout 2025

Cancer Therapy-Related Diarrhea (CTD) Program

As announced, the FDA granted Napo a Type C Meeting in Q2 2025 to discuss the responder analysis results in the prespecified subgroup of patients with breast cancer in Napo's recently conducted Phase 3 [OnTarget](#) trial. Patients with breast cancer accounted for 183 of the 287 participants in this unprecedented prophylactic clinical trial of crofelemer for diarrhea in adults with solid tumors receiving targeted therapy with or without standard chemotherapy. While the initial top line results from the OnTarget study showed that this multicenter, double-blind, placebo-controlled pivotal trial did not meet its primary endpoint for the prespecified analysis of all tumor types, the subgroup analysis in adult breast cancer patients indicates that crofelemer achieved significant results in this subgroup. The company's goal for the meeting is to discuss the most efficient potential pathway to make crofelemer available to adult breast cancer patients for CTD.

The results in breast cancer patients were the subject of a poster presentation on December 11, 2024, at the [San Antonio Breast Cancer Symposium](#), and additional significant results in adult breast cancer patients from the OnTarget study have been accepted for presentation as an oral rapid e-poster

at the [Multinational Association of Supportive Care in Cancer \(MASCC\) Annual Meeting](#) in June 2025 in Seattle, Washington.

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, specifically associated with overactive bowel, which includes symptoms such as chronic debilitating diarrhea, urgency, bowel incontinence, and cramping pain. Jaguar family company Napo Pharmaceuticals focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Jaguar family company Napo Therapeutics is an Italian corporation Jaguar established in Milan, Italy in 2021 focused on expanding crofelemer access in Europe and specifically for orphan and/or rare diseases. Jaguar Animal Health is a Jaguar tradename. Magdalena Biosciences, a joint venture formed by Jaguar and Filament Health Corp. that emerged from Jaguar's [Entheogen Therapeutics Initiative](#) (ETI), is focused on developing novel prescription medicines derived from plants for mental health indications.

For more information about:

Jaguar Health, visit <https://jaguar.health/>

Napo Pharmaceuticals, visit www.napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

Visit the *Make Cancer Less Shitty* patient advocacy program on [Bluesky](#), [X](#), [Facebook](#) & [Instagram](#)

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that crofelemer's mechanism of action may have the potential to provide a novel therapeutic option to reduce TPN and associated complications, including liver, renal, and cognitive deficits, as well as infections from IV infusion, in pediatric MVID and SBS-IF patients, Jaguar's expectation that POC data in MVID may support crofelemer's potential inclusion in the EMA's PRIME program for expedited and assisted regulatory approval and in the FDA's Breakthrough Therapy program for expedited regulatory approval in the US, Jaguar's expectation that additional POC results from IITs will be available throughout 2025, Jaguar's expectation that Napo will meet with the FDA in Q2 2025 and discuss the most efficient potential pathway to make crofelemer available to adult breast cancer patients for CTD, and Jaguar's expectation that additional significant results in adult breast cancer patients from the OnTarget study will be presented at the 2025 MASCC Annual Meeting. 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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