



## **Jaguar Receives Regulatory Clearance in Germany and Italy for Crofelemer for Rare Disease Study - Short Bowel Syndrome with Intestinal Failure (SBS-IF)**

February 19, 2025

***This study, initiated yesterday, is one of five clinical efforts - three proof-of-concept (POC) investigator-initiated trials (IIT) and two Phase 2 studies - of crofelemer for the rare disease indications of SBS-IF and microvillus inclusion disease (MVID) in the US, EU, and/or Middle East/North Africa regions***

***Availability of first IIT proof-of-concept results potentially in H1 2025***

***Crofelemer, Jaguar's novel plant-based prescription drug, has been granted Orphan-Drug Designation by the FDA and the European Medicines Agency (EMA) for both SBS-IF and MVID***

**SAN FRANCISCO, CA / [ACCESS Newswire](#) / February 19, 2025 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#)** ("Jaguar") family companies [Napo Pharmaceuticals](#) ("Napo") and [Napo Therapeutics](#) today announced that the clinical protocol for Napo's Phase 2 study to evaluate the efficacy of crofelemer, Jaguar's novel plant-based anti-secretory prescription drug, for the indication of SBS-IF in adults has received regulatory clearance from health authorities in Italy and Germany, where the trial will be conducted. The study initiated yesterday, February 18, 2025.

"The initiation of this double blind, placebo-controlled study in adult SBS-IF patients is another key milestone for Jaguar," said Lisa Conte, Jaguar's founder, president, and CEO. "This study is one of five clinical efforts in rare diseases - three POC IIT studies and two Phase 2 studies - for crofelemer for the orphan disease indications of SBS-IF and/or MVID in the United States, European Union, and/or Middle East and North Africa (MENA) regions."

"The Company's Phase 2 study to evaluate the efficacy of crofelemer for MVID in pediatric patients has been initiated, as has the independent IIT in the United Arab Emirates to evaluate crofelemer for SBS-IF and MVID in pediatric patients, and the independent IIT in the U.S. to evaluate crofelemer for SBS-IF in adults. The additional IIT is expected to initiate in Q1 2025, with the availability of the first POC IIT result potentially in H1 2025, and with additional POC IIT results expected throughout 2025. In accordance with the guidelines of specific EU countries, published data from clinical investigations in MVID and SBS-IF could support reimbursed early patient access to crofelemer for these debilitating conditions," Conte said.

SBS-IF and MVID, rare and severe diseases requiring intensive parenteral nutrition and support, have severe morbidity and mortality implications and impact the quality of life of both patients and their caregivers. Short bowel syndrome (SBS) affects approximately 10,000 to 20,000 people in the U.S., according to the Crohn's & Colitis Foundation, and it is estimated that the population of SBS patients in Europe is approximately the same size.

Crofelemer has been granted Orphan-Drug Designation by the FDA and the EMA for SBS-IF and MVID.

### **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 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 (Napo) focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo's crofelemer is FDA-approved under the brand name Mytesi® for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. 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](http://www.napopharma.com)

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

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### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that an additional IIT will initiate in Q1 2025, Jaguar's expectation that availability of the first IIT POC result may potentially occur in H1 2025, Jaguar's expectation that additional IIT POC results may be available throughout 2025, and Jaguar's expectation that, in accordance with the guidelines of specific EU countries, published data from clinical investigations could support early patient access to crofelemer for SBS-IF or MVID in these countries. 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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