Jaguar Health Provides Updates on Orphan Disease Intestinal Failure Development Program for Crofelemer

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Enrollment in company's first-of-its-kind placebo-controlled Phase 2 study to evaluate the efficacy of crofelemer for microvillus inclusion disease (MVID) in pediatric patients has reached approximately 25%

As recently announced, initial proof-of-concept results of the ongoing investigator-initiated trial (IIT) show crofelemer reduced the required total parenteral nutrition in patients with intestinal failure due to MVID and short bowel syndrome by up to 27% and 12.5% respectively; data from the third patient enrolled is expected

Company strategy: Seek business development partnerships for license to develop and commercialize Jaguar's intestinal failure products, resulting in non-dilutive funding for Jaguar

SAN FRANCISCO, CA / ACCESS Newswire / June 23, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar) today provided updates on the company's orphan disease intestinal failure program. Jaguar, through Jaguar family companies Napo Pharmaceuticals (Napo) and Napo Therapeutics, is currently supporting two independent proof-of-concept investigator-initiated trials (IITs), and conducting two placebo-controlled Phase 2 studies, of crofelemer, Jaguar's novel plant-based anti-secretory prescription drug, in patients with intestinal failure due to microvillus inclusion disease (MVID) and short bowel syndrome (SBS-IF) in the United States, European Union, and/or Middle East/North Africa regions.

As announced, and as presented April 26, 2025 at the Annual ELITE PED-GI Congress, initial proof-of-concept results from the ongoing exploratory, single-arm open label non-randomized IIT of crofelemer in Abu Dhabi in pediatric intestinal failure patients show that crofelemer reduced the required total parenteral nutrition (TPN) and supplementary intravenous fluids in the first participating MVID patient by up to 27% and in the first participating SBS-IF patient by up to 12.5%. In addition, this data showed that crofelemer reduced stool volume output and/or frequency of watery stools, and increased urine output - an indicator of improved nutrient oral absorption. Data from the third patient enrolled in the IIT is expected.

Completion of Napo's randomized double-blind, placebo-controlled Phase 2 study of crofelemer in pediatric MVID patients is expected in mid-2026 as planned.

"Our strategy is to seek business development partnerships for license rights for development and commercialization of Jaguar's intestinal failure products - with the goal of generating non-dilutive funding for Jaguar," said Lisa Conte, Jaguar's Founder and CEO. "I attended the BIO International Convention in Boston last week and took part in productive meetings at the event."

"Given the ultrarare nature of MVID, and the groundbreaking initial proof-of-concept results from the ongoing 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 Conte.

"We're excited to report that enrollment in the company's first-of-its-kind placebo-controlled Phase 2 study to evaluate the efficacy of crofelemer for MVID in pediatric patients is at approximately 25% and patient screening is continuing. For the company's placebo-controlled Phase 2 study to evaluate the efficacy of crofelemer for SBS-IF in adults, enrollment is above 10%, and patient screening is continuing," said Conte. "Additionally, enrollment is continuing in the two ongoing proof-of-concept IITs. These are important milestones in development efforts for crofelemer for the treatment and management of intestinal failure related to these devastating orphan diseases and will continue to generate IIT data."

Based on the initial findings of the ongoing IIT in Abu Dhabi, crofelemer's paradigm-shifting 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 patients with intestinal failure due to MVID and short bowel syndrome. The observed groundbreaking 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.

The initial proof-of-concept data in MVID supports crofelemer's potential inclusion in the European Medicines Agency's (EMA) PRIMEprogram that may accelerate regulatory approval pathways in the EU. This data may also support qualification of crofelemer for the FDA's Breakthrough Therapyprogram for expedited regulatory approval in the US. Additional proof-of-concept results from IITs are expected throughout 2025 and will provide additional preliminary data on the safety and potential effectiveness of crofelemer for these highly unmet clinical needs. 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.

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 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

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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 completion of Napo's Phase 2 study of crofelemer in pediatric MVID patients will occur mid-2026, Jaguar's expectation that the two ongoing proof-of-concept IITs will continue to generate data, Jaguar's expectation that data from the third patient enrolled in the IIT in Abu Dhabi is expected, Jaguar's expectation that its strategy of seeking business development partnerships for license rights for development and commercialization of Jaguar's intestinal failure products may support generation of non-dilutive funding for Jaguar, 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 of crofelemer for MVID, 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 proof-of-concept data in MVID may support crofelemer's potential inclusion in the EMA's PRIME program for expediated and assisted regulatory approval and in the FDA's Breakthrough Therapy program for expedited regulatory approval in the US, Jaguar's expectation that additional proof-of-concept results from IITs will be available throughout 2025, and Jaguar's expectation that published data from clinical investigations in MVID and SBS-IF could support reimbursed early patient access to crofelemer for MVID and SBS-IF. 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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