Proof-of-Concept Data for Rare Disease Indications MVID and SBS-IF for Jaguar Health's Crofelemer to be Presented at April 2025 ELITE PED-GI Congress

April 17, 2025

Crofelemer, a novel plant-based anti-secretory prescription drug, has been granted Orphan Drug Designation by the FDA and the European Medicines Agency (EMA) for both short bowel syndrome (SBS) and microvillus inclusion disease (MVID) and is being evaluated to serve as a potential therapeutic option to manage intestinal failure in these patients

There are currently no approved drug treatments for MVID, an ultrarare pediatric disease characterized by severe diarrhea and malabsorption that requires intensive parenteral support for nutritional and fluid management

Proof-of-concept data in MVID from this study would provide support for crofelemer's potential inclusion in the EMA's PRIME program for novel medicines targeting unmet medical needs and the FDA's Breakthrough Therapies program

SAN FRANCISCO, CA / ACCESS Newswire / April 17, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar) family companies Napo Pharmaceuticals (Napo) and Napo Therapeutics today announced that preliminary results from the ongoing pediatric investigator-initiated trial (IIT) of a novel liquid formulation of crofelemer, Jaguar's novel plant-based anti-secretory prescription drug, for various congenital diarrheal disorders (CDD), including MVID and SBS with intestinal failure (SBS-IF), will be presented by Dr. Mohamad Miqdady at the April 24-26, 2025 Annual ELITE PED-GI Congress in Abu Dhabi in the United Arab Emirates.

MVID and SBS-IF, rare orphan 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. There are currently no approved drug treatments for MVID. A key value driver would be a reduction in total parenteral nutrition (TPN).

"Patients with MVID and SBS-IF suffer from devastating diarrhea and dehydration caused by these debilitating, lifelong conditions. These patients are frequently on TPN for as long as 20 hours a day, seven days a week - and TPN carries a significant risk of morbidity, including infections, metabolic complications, and liver problems," said Dr. Miqdady, the principal investigator for this study. "I look forward to presenting preliminary, proof-of-concept results from this study at the ELITE PED-GI Congress."

This ongoing proof-of-concept study is evaluating crofelemer's potential to be safely administered to patients with MVID, SBS-IF, and other CDDs in escalating doses, improve stool formation, improve the absorption of nutrients, and lower TPN needs - which have never been achieved in an MVID patient. The study also provides the opportunity to evaluate whether any potential benefit provided by crofelemer in participating patients ceases after treatment with crofelemer is discontinued.

Napo expects that if even just a very small number of MVID patients show benefit with crofelemer, this may potentially allow pathways for regulatory approval in the US and other regions and qualify crofelemer for participation in PRIME, a European Medicines Agency (EMA) program providing enhanced interaction and early dialogue with drug developers of novel medicines targeting unmet medical needs; early patient access in certain EU countries; and in the U.S. Food and Drug Administration's (FDA) Breakthrough Therapies program. If a drug is designated as breakthrough therapy, the FDA will expedite the development and review of the drug.

This study is being conducted at Sheikh Khalifa Medical City (SKMC), a flagship tertiary hospital in the United Arab Emirates and the largest teaching medical center in Abu Dhabi, by Dr. Mohamad Miqdady, a recognized leader in pediatric gastroenterology who is SKMC's Division Chief of the Pediatric Gastroenterology, Hepatology & Nutrition Division.

Jaguar is supporting multiple clinical investigations, including additional IITs, for crofelemer together with additional clinical studies in adult SBS-IF and pediatric MVID patients in the US, European Union, and/or Middle East/North Africa regions. POC 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.

Dr. Miqdady is an American board-certified pediatric GI, hepatology and nutrition professor at Khalifa University in Abu Dhabi, and serves as a member of Napo's Scientific Advisory Board. He completed his Fellowship in Pediatric Gastroenterology at Baylor College of Medicine and Texas Children's Hospital in Houston.

The Annual ELITE PED-GI Congress is designed to provide information about high level, clinically significant updates and comprehensive trends relevant to the practice of pediatric gastroenterological, nutrition and liver disorders. Napo is a Bronze-level sponsor of the 2025 Annual ELITE PED-GI Congress.

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. 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 POC data for MVID and SBS-IF for crofelemer will be presented at the April 2025 Annual ELITE PED-GI Congress, the expectation that a key value driver would be a reduction in TPN in MVID and SBS-IF patients, the expectation that crofelemer's mechanism of action may have the potential to serve as a therapeutic option to manage intestinal failure in patients with MVID and SBS-IF and improve the quality of life of these patients receiving chronic TPN, Jaguar's expectation that, if even just a very small number of MVID patients show benefit with crofelemer, this may potentially allow pathways for regulatory approval in the US and other regions and qualify crofelemer for participation in PRIME, early patient access in certain EU countries, and in the FDA's Breakthrough Therapies program for MVID, Jaguar's expectation that POC results from IITs will be available throughout 2025, and Jaguar's expectation that, 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. 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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SOURCE: Jaguar Health, Inc.

press release