Jaguar Health Announces Submission of Clinical Trial Applications for Crofelemer for the Rare Disease Indications Microvillus Inclusion Disease (MVID) and Short Bowel Syndrome (SBS) in Europe

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Jaguar's novel plant-based prescription drug crofelemer has been granted Orphan Drug Designation by the FDA and the European Medicines Agency for both MVID and SBS

SAN FRANCISCO, CA / ACCESSWIRE / May 9, 2024 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar") today announced that Jaguar family companies Napo Pharmaceuticals ("Napo") and Napo Therapeutics have submitted a Clinical Trial Application (CTA) to the Italian and German health authorities to initiate a phase 2 clinical trial of Jaguar's novel plant-based prescription drug crofelemer for treatment of short bowel syndrome (SBS) with intestinal failure in adults. Napo Therapeutics has also submitted a CTA to AIFA, the Italian health authority, for the conduct of a clinical trial in pediatric patients with microvillus inclusion disease (MVID), and the approval request process is also underway for this trial in the United Arab Emirates with Dubai Health. The MVID clinical trial is being conducted under an active US Investigational New Drug (IND) in the US.

"We're very pleased that these important CTAs have been submitted," said Lisa Conte, Jaguar's president and CEO. "This is a key regulatory milestone in our ongoing development efforts for a novel powder formulation of crofelemer for oral solution for patients with MVID and SBS with intestinal failure - two devastating and often catastrophic rare diseases for patients, who are frequently on parenteral nutrition for as long as 20 hours a day, seven days a week."

"As previously announced, Jaguar, with strong leadership and participation from Napo Pharmaceuticals and Napo Therapeutics, is also supporting investigator-initiated proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure in the US, EU and Middle East/North Africa (MENA) regions, with proof-of-concept results expected in 2024. Additionally, in August 2023 the FDA activated Napo Pharmaceuticals' Investigational New Drug (IND) application for a novel formulation of crofelemer for the treatment of MVID, which allows us to initiate our planned US-based phase 2 trial of crofelemer for treatment of this indication in pediatric MVID patients," Conte said. "In accordance with the guidelines of specific EU countries, published data from clinical investigations in MVID and SBS could support early patient access to crofelemer for these debilitating conditions in those countries."

MVID, an ultra-rare congenital diarrheal disorder, is a severe infantile disease characterized by diarrhea, malabsorption, and acid/base instability, requiring intensive parenteral support for nutritional and fluid management, and there are currently no approved drug treatments.

Some SBS patients are subject to intestinal failure, often requiring parenteral nutrition (PN) from a few days up to 7 days a week. Intestinal failure is associated with significant morbidity and mortality; and high medical expenses associated with PN. SBS patients with intestinal failure also have severe chronic diarrhea, and the associated sequelae from diarrhea, including significant dehydration, metabolic acidosis or alkalosis and malnutrition, and other secondary symptoms, and these symptoms emerge either early or late, and many times become life-threatening.

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. Napo Pharmaceuticals' crofelemer drug product candidate is the subject of the OnTarget study, a pivotal Phase 3 clinical trial for preventive treatment of chemotherapy-induced overactive bowel (CIOB) in adults with cancer on targeted 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
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, in accordance with the guidelines of specific EU countries, published data from clinical investigations in MVID and SBS could support early patient access to crofelemer for these conditions in those 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 a number of 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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