Jaguar Health Announces First Patient Dosed in Investigator-Initiated Trial (IIT) Evaluating Crofelemer for the Rare Disease Indication of Microvillus Inclusion Disease (MVID), with Proof-of-Concept (POC) Data Potentially Available H1 2025

January 22, 2025

Trial taking place at Sheikh Khalifa Medical City, a flagship tertiary hospital in the United Arab Emirates

POC data generated from this study could potentially lead to reimbursed early patient access in certain European countries for crofelemer for MVID

Crofelemer, Jaguar's novel plant-based prescription drug, has been granted Orphan Drug Designation by the FDA and the European Medicines Agency for both MVID and short bowel syndrome with intestinal failure (SBS-IF)

SAN FRANCISCO, CA / ACCESS Newswire / January 22, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar) family companies Napo Pharmaceuticals (Napo) and Napo Therapeutics today announced that the first patient has been dosed in the independent investigator-initiated POC trial of crofelemer, Jaguar's novel plant-based anti-diarrheal prescription drug, for the rare disease indication of MVID in pediatric patients. POC data generated from this study potentially in the first half of 2025 could lead to reimbursed early patient access to crofelemer for this indication in certain European countries.

The trial will also include pediatric patients with SBS-IF. It is being conducted by Dr. Mohamad Miqdady, a recognized leader in pediatric gastroenterology who is the Division Chief of the Pediatric Gastroenterology, Hepatology & Nutrition Division at Sheikh Khalifa Medical City (SKMC), a flagship tertiary hospital in the UAE and the largest teaching medical center in Abu Dhabi.

"Dosing of the first patient in this unblinded study is an important milestone in clinical development efforts for crofelemer for MVID and SBS-IF - both of which are rare and severe diseases requiring intensive parenteral nutrition and support," said Lisa Conte, Jaguar's founder, president, and CEO.

The trial is taking place at SKMC. Autosomal recessive disorders and congenital anomalies such as MVID are more prevalent in the Middle East and North Africa (MENA) region.

"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 MVID and/or SBS-IF in the United States, European Union, and/or MENA regions," Conte said. "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 U.S. to evaluate crofelemer for SBS-IF in adults. The two additional studies are expected to initiate in early 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."

MVID and SBS-IF, 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.

MVID is a pediatric disease with an estimated prevalence of a couple of hundred patients globally. It is characterized by severe diarrhea and malabsorption, requiring intensive parenteral support for nutritional and fluid management. Each MVID patient is a unique patient; their journey requires very careful management of their nutritional needs, and there are currently no approved drug treatments for MVID.

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. Pediatric SBS is a malabsorptive condition caused by surgical intestinal resection due to congenital abnormalities, vascular insufficiency or severe inflammatory intestinal disease. The incidence of pediatric SBS varies between 0.02% to 1.2% of live births.[1] Based on an estimate of 3.6 million live births in the U.S. in 2023,[2] the maximal incidence of pediatric SBS is estimated to be approximately 43,000.

Pediatric SBS-IF is associated with significant morbidity and mortality; and high medical expenses, and the patients also have severe chronic diarrhea. The associated sequelae from chronic diarrhea include significant dehydration, metabolic acidosis or alkalosis, and malnutrition.

Crofelemer has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency for MVID and SBS.

Dr. Miqdady is an Adjunct Professor at Khalifa University's medical school 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.

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
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 another IIT and another Phase 2 study of crofelemer will initiate in early Q1 2025, Jaguar's expectation that POC data from the MVID IIT in Abu Dhabi may be available in H1 2025, Jaguar's expectation that additional POC IIT results for crofelemer 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.

[1] Beth A. Carter, MD, et al. Outcomes from a 12-Week, Open-Label, Multicenter Clinical Trial of Teduglutide in Pediatric Short Bowel Syndrome. The Journal of Pediatrics, 2017; 181:102-11
[2] https://www.ncbi.nlm.nih.gov/books/NBK607756/

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