



Independent Study Conducted at Boston Children's Hospital, Harvard Medical School, Shows Potential Utility of Jaguar Health's Crofelemer for Treatment of MVID, a Rare Childhood Disease

October 19, 2023

MVID, for which there are no approved drug treatments, is a life-threatening and ultra-rare autosomal recessive disease that affects newborns and children, leading to intestinal failure, significant morbidity and even death from severe secretory diarrhea

Crofelemer has been granted Orphan Drug Designation by the FDA and the European Medicines Agency for MVID, and the Company's Investigational New Drug application for crofelemer for treatment of MVID is now activated by the FDA

SAN FRANCISCO, CA / ACCESSWIRE / October 19, 2023 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) ("Jaguar" or the "Company") today announced that an independent, investigator-initiated study evaluating the efficacy of crofelemer, the Company's plant-based prescription drug, for the treatment of microvillus inclusion disease (MVID) has been published in *The Journal of Clinical Investigation* (JCI), a peer-reviewed medical journal covering biomedical research.

The results of this *in vitro* study demonstrate that crofelemer has the clinical potential for symptomatic therapy and electrolyte and fluid management in MVID patients. Click [here](#) to view the published study.

MVID 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.

This study, titled "Patient-derived enteroids provide a platform for the development of therapeutic approaches in microvillus inclusion disease," was conducted by Jay Thiagarajah, MD, PhD, who is Co-Director of the Congenital Enteropathy Program, and an Attending Physician in the Division of Gastroenterology, Hepatology and Nutrition, at Boston Children's Hospital, Harvard Medical School, where Dr. Thiagarajah also serves as Assistant Professor of Pediatrics.

MVID patients commonly face intestinal failure - a catastrophic health situation that also often afflicts patients with short bowel syndrome (SBS). Crofelemer has been granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for both MVID and SBS. Jaguar is supporting investigator-initiated and investigator IND 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 results expected before the end of 2023 and in 2024. In accordance with the guidelines of specific European Union countries, published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID, potentially in 2024, for these debilitating conditions.

The Company's Investigational New Drug application for crofelemer for the treatment of MVID was activated by the FDA August 7, 2023.

About Crofelemer

Crofelemer is the only oral prescription drug approved by the FDA under botanical guidance. It is plant-based, extracted and purified from the red bark sap of the *Croton lechleri* tree in the Amazon Rainforest. Jaguar family company 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, and bowel incontinence. 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, an ongoing 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

Visit Jaguar on LinkedIn: <https://www.linkedin.com/company/jaguar-health/>

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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 results of investigator-initiated and investigator IND proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure will be available before the end of 2023 and in 2024, and Jaguar's expectation that published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID, potentially in 2024, for these 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 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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