FDA Grants Orphan Drug Designation to Jaguar Health for Crofelemer for Microvillus Inclusion Disease (MVID), a Second Rare Disease Indication in the US

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Crofelemer was previously granted Orphan Drug Designation by the FDA for short bowel syndrome

SAN FRANCISCO, CA / ACCESSWIRE / February 28, 2023 / Jaguar Health (NASDAQ:JAGX) ("Jaguar" or the "Company") today announced that the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) to crofelemer for the indication of microvillus inclusion disease (MVID), a rare congenital diarrheal disorder (CDD) condition, following review of the ODD application the Company submitted to the FDA.

"This is another very welcome development for our oral botanical drug, crofelemer, a new molecular entity that now holds four orphan designations, as crofelemer previously received ODD for MVID from the European Medicines Agency (EMA) and for short bowel syndrome (SBS) from both the FDA and the EMA," said Lisa Conte, Jaguar's president and CEO.

CDD and SBS are the initial focus of Napo Therapeutics, the Italian corporation established by Jaguar in Milan, Italy in 2021 with a mission to expand crofelemer access in Europe for the treatment and management of orphan and rare disease indications.

Jaguar is currently supporting investigator-initiated proof-of-concept studies of crofelemer in patients with SBS or CDD with intestinal failure, focused on obtaining proof-of-concept (POC) of reduction of requirements of parenteral support including parenteral nutrition and/or intravenous fluids, throughout 2023. In accordance with the guidelines of specific European Union countries, publications of POC data from these trials could support early patient access to crofelemer for SBS or CDD with intestinal failure in 2023 through programs in Europe. Early access programs are revenue generating, and reimbursable for participating patients.

"CDDs are a group of inherited chronic enteropathies characterized by heterogeneous etiology, and each type of CDD is thus a different disease with a different pathophysiologic mechanism," said Pravin Chaturvedi, PhD, Jaguar's Chair of the Scientific Advisory Board and Chief Scientific Officer. "MVID is a life-threatening and rare autosomal recessive disease that affects newborns and children and leads to significant morbidity and even death from severe secretory diarrhea."

CDD and SBS patients are subject to intestinal failure, often requiring parenteral nutrition (PN) up to 7 days a week. These conditions are associated with significant morbidity and mortality; and high medical expenses associated with PN. CDD and SBS patients also share a primary common symptom: 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.

The Orphan Drug Act (ODA) in the US provides for granting special status to a small molecule drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan drug designation (or sometimes "orphan status"). Orphan drug designation qualifies the sponsor of the drug for various development incentives, including tax credits for qualified clinical testing and relief of filing fees. Additionally, the ODA provides a seven-year period of marketing exclusivity to the first sponsor who obtains marketing approval for a designated orphan drug.

In the EU, receipt of ODD supports some specific regulatory pathways, and sponsors who obtain ODD for their drug can benefit from Scientific Advice from the EMA for clinical trials for the orphan indication and receive market exclusivity for a period of ten years once the medicine is approved for commercialization.

About Crofelemer

Crofelemer is the only oral FDA approved drug under botanical guidance. It is plant-based, extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon Rainforest. Napo Pharmaceuticals, Jaguar Health's wholly owned U.S. subsidiary, 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 Jaguar Health, Napo Pharmaceuticals, Napo Therapeutics & Jaguar Animal Health

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, sustainably-derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human pharmaceuticals from plants harvested responsibly from rainforest areas. Our crofelemer drug product candidate is the subject of the OnTarget study, an ongoing pivotal Phase 3 clinical trial for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A.

(f/k/a Napo EU S.p.A.), an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe. Jaguar Animal Health is a tradename of Jaguar Health.

For more information about Jaguar Health, please visit https://jaguar.health. For more information about Napo Pharmaceuticals, visit www.napopharma.com. For more information about Napo Therapeutics, visit napotherapeutics.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's expectation that publications of POC data could support early patient access to crofelemer for SBS or CDD with intestinal failure in 2023 through programs in Europe. 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.

Contact:

hello@jaguar.health
Jaguar-JAGX

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