



Jaguar Health Announces Napo Therapeutics' Submission of Orphan Drug Designation Application to the European Medicines Agency for Crofelemer for a Severe Congenital Diarrheal Disorder (CDD) Condition

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Microvillus inclusion disease (MVID) is a life-threatening and rare autosomal recessive disease that affects newborns and children and leads to significant morbidity and mortality from severe secretory diarrhea

SAN FRANCISCO, CA / ACCESSWIRE / May 25, 2022 / Jaguar Health (NASDAQ:JAGX) today announced that Napo Therapeutics, the Italian corporation established by the company in Italy in 2021 that focuses on expanding crofelemer access in Europe, has submitted an Orphan Drug Designation (ODD) application for crofelemer for a rare congenital diarrheal disorder (CDD) condition called microvillus inclusion disease (MVID) to the European Medicines Agency (EMA). The submission is the first step of the process; the review by the EMA's Committee for Orphan Medicinal Products (COMP) will start after the validation of the submission.

"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 pathogenetic mechanism," said Martire Particco, MD, Chief Medical Officer of Napo Therapeutics. "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."

CDDs share a primary common symptom: chronic diarrhea, and therefore secondary symptoms associated with diarrhea, including significant dehydration, metabolic acidosis or alkalosis and malnutrition, among other secondary symptoms, and these symptoms expeditiously emerge and become life-threatening.

Napo Therapeutics' mission is to provide access to Jaguar Health's proprietary first-in-class plant-based medicine crofelemer in Europe to address such significant rare disease indications. The company's initial focus is on clinical development and future registration in Europe of crofelemer for debilitating orphan disease target indications starting with short bowel syndrome (SBS).

The evaluation [process](#) for the ODD application takes approximately 90 days from acceptance. Sponsors who obtain orphan designation 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.

"We are very pleased that the orphan drug designation application for crofelemer for MVID is now with the EMA," said Massimo Mineo, CEO of Napo Therapeutics. "Upon receipt of a positive opinion from the COMP on this application, crofelemer will be eligible for granting of orphan drug designation by the EMA for this indication. Receipt of orphan drug designation would support some specific regulatory pathways for this serious form of CDD, which represents a significant unmet medical need."

About Crofelemer

Crofelemer is a botanical (plant-based) drug extracted and purified from the red bark sap, also referred to as "dragon's blood," 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, Jaguar Animal Health, Napo Pharmaceuticals, & Napo Therapeutics

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Animal Health is a tradename of Jaguar Health. 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. 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.

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

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." 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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