



Jaguar Health Provides Updates on Presentation at the World Congress of Gastroenterology About Crofelemer for Pediatric Short Bowel Syndrome (SBS) and Congenital Diarrheal Disorders (CDD) by Third-Party Investigator

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Jaguar is also supporting a third-party investigator evaluating crofelemer for eosinophilic colitis, another rare pediatric gastrointestinal condition

Proof-of-concept data for the use of crofelemer for pediatric orphan or rare disorders is expected to provide additional support for the potential for expanded patient access to crofelemer through programs in Europe in late 2023

SAN FRANCISCO, CA / ACCESSWIRE / December 19, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX) and Napo Therapeutics, the corporation established by Jaguar in Italy in 2021 that focuses on expanding crofelemer access for orphan and rare diseases in Europe, today announced that an update regarding a third-party clinical investigation of crofelemer for pediatric short bowel syndrome (SBS) and congenital diarrheal disorders (CDD) was presented at the [World Congress of Gastroenterology](#), a global GI conference that took place December 12-14, 2023 in Dubai in the United Arab Emirates (UAE). This update was provided by the clinical investigator, Dr. Mohamad Miqdady, Division Chief of the Pediatric Gastroenterology, Hepatology & Nutrition Division at Sheikh Khalifa Medical City in the UAE.

Dr. Miqdady is also expected to make a presentation about this trial in May 2023 at the [Annual Elite Ped-GI Congress](#) in Abu Dhabi in the UAE.

"The update at the Annual Elite Ped-GI Congress is part of a series of planned presentations in the first half of 2023 on investigator-initiated proof-of-concept clinical studies of crofelemer for pediatric gastrointestinal orphan or rare diseases which remain a significant unmet medical need," said Lisa Conte, Jaguar's president and CEO. "Clinical studies of crofelemer for addressing pediatric SBS and CDD conditions are expected to be conducted throughout 2023. In accordance with the guidelines of specific EU countries, published data from such clinical investigations could support early patient access of crofelemer for pediatric SBS or CDD, especially for patients with intestinal failure requiring parenteral support, by late 2023 through programs in Europe for these debilitating conditions. Participation in Early Access Programs in some EU countries provides an opportunity for reimbursement while impacting the morbidity and high cost of care for these chronic unmet needs. SBS affects approximately 10,000 to 20,000 people in the EU and similar prevalence is reported for the U.S. Despite limited treatment options, the global adult and pediatric SBS market alone exceeded \$568 million in 2019 and is expected to reach \$4.6 billion by 2027, according to a report by Vision Research Reports."

As previously announced, the European Medicines Agency (EMA) granted Orphan Drug Designation (ODD) for crofelemer for SBS as well as microvillus inclusion disease (MVID), a rare pediatric CDD condition. The recognition of ODD in Europe for crofelemer for SBS and MVID are key Napo Therapeutics milestones under the company's exclusive crofelemer license agreement with Jaguar, and receipt of these ODDs supports opportunities for accelerated regulatory pathways.

Crofelemer received ODD in the U.S. for SBS from the U.S. Food and Drug Administration (FDA) in 2017, and Jaguar is awaiting a response from the FDA regarding the ODD application the company submitted to the FDA for crofelemer for MVID in the U.S.

Jaguar is also partially supporting a third-party clinical investigation evaluating crofelemer for a patient with eosinophilic colitis (EC), a rare pediatric diarrheal condition.

About Crofelemer

Crofelemer is a novel, oral plant-based medicine 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 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, non-opioid, and 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.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar Health's expectation that Dr. Mohamad Miqdady will make a presentation about a proof-of-concept trial of crofelemer for SBS and CDD in May 2023 at the Annual Elite Ped-GI Congress, Jaguar Health's expectation that this planned update at the Annual Elite Ped-GI Congress will be part of a series of presentations in the first half of 2023 on investigator-initiated proof-of-concept clinical studies of crofelemer for pediatric gastrointestinal orphan or rare diseases, Jaguar Health's expectation that clinical studies of crofelemer for SBS and CDD conditions will be conducted throughout 2023, and Jaguar Health's expectation that published data from such clinical investigations could support early patient access of crofelemer for pediatric SBS or CDD by late 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.

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