



Jaguar Health Announces Completion of Third-party, Investigator-Initiated Study of Crofelemer, which is Expected to Support Orphan Drug Designation (ODD) for Crofelemer for Congenital Diarrheal Disorders (CDD)

February 1, 2022

Study results expected to be described in upcoming presentations and publications

CDD patients face intestinal failure (IF), similar to patients suffering from short bowel syndrome (SBS) - the priority focus for ODD development for crofelemer

SAN FRANCISCO, CA / ACCESSWIRE / February 1, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX) and Napo Pharmaceuticals, the company's wholly owned subsidiary, today announced the completion of a third-party, investigator-initiated preclinical enterocyte (intestinal cell) *in vitro* study to evaluate the effects of crofelemer, Napo Pharmaceuticals' plant-based prescription drug, on certain genetic defects that result in specific forms of congenital diarrheal disorders. Jaguar Health believes that these study results will support certain requests received from the Office of Orphan Products Development at the U.S. Food and Drug Administration (FDA) in response to the Orphan Drug Designation (ODD) application Napo Pharmaceuticals filed with the FDA for crofelemer for congenital diarrheal disorders (CDD) in infants and children.

"We believe the data from this study will support the rare disease business model that Napo Therapeutics, the majority owned company Jaguar Health established in Italy in 2021, is pursuing in Europe under its exclusive license for crofelemer from Jaguar Health," said Jaguar Health president and CEO, Lisa Conte, who is also the chairman of the board of Milan, Italy-based Napo Therapeutics S.p.A.

Napo Therapeutics' mission is to provide access to crofelemer in Europe to address significant rare/orphan disease indications, including, initially, CDD and short bowel syndrome with intestinal failure (SBS-IF). Napo Therapeutics has been granted ODD for crofelemer for short bowel syndrome (SBS) in the European Union by the European Medicines Agency, and Napo Pharmaceuticals has been granted ODD for crofelemer for SBS in the U.S. by the FDA.

"CDD patients have intestinal failure and morbidity resulting in a failure to thrive due to malabsorption of nutrients and need parenteral nutrition. We believe the novel mechanism of action of crofelemer may have considerable potential to manage the severe secretory loss of electrolytes and fluid resulting in dehydration. There are currently no therapies for CDD except parenteral nutrition. Thus, crofelemer may reduce the associated morbidity and mortality of CDD, with the added advantage of lessening the need for parenteral nutrition," said Conte.

The Orphan Drug Act of 1983, a law passed in the U.S. to facilitate development of drugs for rare diseases, provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status"). Orphan designation qualifies the sponsor of the drug for various development incentives, including tax credits for qualified clinical testing and relief of filing fees.

About Congenital Diarrheal Disorders (CDD)

CDD is a group of rare, chronic intestinal channel diseases which occur exclusively in early infancy and are characterized by severe, lifelong diarrhea and a lifelong need for nutritional intake either parenterally or with a feeding tube. CDDs are related to specific genetic defects inherited as autosomal recessive traits, and the incidence of CDDs is much more prevalent in regions where consanguineous marriage is part of the culture. CDDs are directly associated with serious secondary conditions including dehydration, metabolic acidosis, and failure to thrive, prompting the need for immediate therapy to prevent death and limit lifelong disability.

About Jaguar Health, Inc., Jaguar Animal Health, Napo Pharmaceuticals, Inc. & Napo Therapeutics S.p.A.

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, specifically 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 gastrointestinal pharmaceuticals from plants harvested responsibly from rainforest areas. Jaguar Health is the majority shareholder of Napo Therapeutics 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. For more information about Napo Therapeutics, visit <https://napotherapeutics.com>.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that the results of the third-party, investigator-initiated preclinical enterocyte study will support ODD for crofelemer for CDD, the expectation that these study results will be described in upcoming presentations and publications, Jaguar Health's belief that these study results will support certain requests received from the Office of Orphan Products Development at the FDA in response to the ODD application Napo Pharmaceuticals filed with the FDA for crofelemer for CDD in infants and children, Jaguar Health's belief that the data from this study will support Napo Therapeutics' rare disease business model, Jaguar Health's belief that the novel mechanism of action of crofelemer may have considerable potential to manage the severe secretory loss of electrolytes and fluid resulting in dehydration, and Jaguar Health's belief that crofelemer may reduce the associated morbidity and mortality of CDD, with the added advantage of lessening the need for parenteral nutrition. 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. Some of the factors that could affect our actual results are included in the periodic reports on Form 10-K and Form 10-Q that we file with the Securities and Exchange Commission. 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:

Peter Hodge
Jaguar Health, Inc.
phodge@jaguar.health
Jaguar-JAGX

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