Jaguar Health Announces FDA Activation of Third-Party Investigational New Drug (IND) Application for Evaluation of Crofelemer for Treatment of Uncontrolled Diarrhea in Patient with Short Bowel Syndrome (SBS)

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Napo Pharmaceuticals, a Jaguar Health company and the manufacturer of crofelemer, is supporting this physician-generated IND

SAN FRANCISCO, CA / ACCESSWIRE / August 1, 2023 / Jaguar Health (NASDAQ:JAGX) ("the Company") today announced the activation by the U.S. Food and Drug Administration (FDA) of a physician-requested Investigational New Drug (IND) application to evaluate crofelemer for treatment of uncontrolled diarrhea in a patient with short bowel syndrome (SBS), a rare and complex condition characterized by diarrhea and/or severe malabsorption of fluids and nutrients. Napo Pharmaceuticals, a Jaguar company, is supporting this investigator-initiated trial of crofelemer, the Company's oral anti-diarrheal prescription drug.

"I am very happy that this IND has been acknowledged by the FDA and that this study to evaluate use of crofelemer to address uncontrolled diarrhea in my patient with SBS may proceed," said Charles Conte, MD, Chief of Surgical Oncology at Northwell Health. "SBS resulting from surgical bowel resection due to cancer diagnosis is a debilitating condition. Our hope is that by potentially relieving the debilitating diarrhea with crofelemer treatment, we can improve the patient's nutritional status and prevent exposing the patient to the toxicities associated with parenteral nutrition."

"Napo Pharmaceuticals received a request from Dr. Conte for emergency use of crofelemer to address the urgent medical need of an SBS patient's deteriorating condition due to severe diarrhea, with the goal of keeping the patient off of parenteral nutrition (PN) and/or minimizing PN requirements," said Pravin Chaturvedi, PhD, Jaguar's Chair of the Scientific Advisory Board and Chief Scientific Officer. "We are pleased to provide support for this study."

Some SBS patients are subject to intestinal failure, often requiring PN from a few to up to 7 days a week. Intestinal failure is associated with significant morbidity and mortality; and high medical expenses associated with PN. SBS patients with intestinal failure also have 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.

In June 2023, Napo Pharmaceuticals submitted an IND application to the FDA for a powder formulation of crofelemer for oral solution for the treatment of microvillus inclusion disease (MVID), an ultrarare congenital diarrheal disorder (CDD) that affects newborns and children, leading to intestinal failure, significant morbidity and even death from severe secretory diarrhea. The Company is supporting investigator-initiated proof-of-concept studies of crofelemer for SBS with intestinal failure and MVID in the European Union and Middle East/North Africa (MENA) regions. In accordance with the guidelines of specific EU 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.

Crofelemer has been granted Orphan Drug Designation (ODD) by the FDA and the European Medicines Agency (EMA) for SBS and MVID. The ODD program in both the U.S. and European Union qualifies sponsors to receive potential incentives to develop therapies for the diagnosis, prevention, or treatment of rare diseases or conditions.

About Crofelemer

Crofelemer is a first-in-class chloride ion channel modulator, and the only oral FDA approved drug under botanical guidance. It is plant-based, extracted and purified from the red bark sap of the *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 Therapeutics S.p.A,

Jaguar Health 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. 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.

For more information about Jaguar Health, please visit https://jaguar.health. 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 expectation that published data from proof-of-concept studies of crofelemer for SBS with intestinal failure and MVID could support reimbursed early patient access to crofelemer for these debilitating conditions, potentially in 2024. 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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