Napo Pharmaceuticals, a Jaguar Health Company, Announces Activation by FDA of Investigational New Drug (IND) Application for Crofelemer for Treatment of Microvillus Inclusion Disease

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SAN FRANCISCO, CA / ACCESSWIRE / August 8, 2023 / Napo Pharmaceuticals Inc. (Napo), a Jaguar Health, Inc. (NASDAQ:JAGX) company, today announced the activation by the U.S. Food and Drug Administration (FDA) of the Investigational New Drug (IND) application for a new crofelemer powder for oral solution formulation for the treatment of microvillus inclusion disease (MVID), an ultra-rare congenital diarrheal disorder (CDD).

"We were very pleased to hear that the FDA has communicated that we may proceed with the proposed phase 2 clinical trial for crofelemer for treatment of MVID in pediatric patients with a novel formulation of crofelemer," said Lisa Conte, Napo and Jaguar's President and CEO. "MVID is a life-threatening and rare autosomal recessive disease that affects newborns and children, leading to intestinal failure, significant morbidity, and even death from severe secretory diarrhea. While there are currently no approved therapeutic treatments for MVID, parenteral nutrition (PN), the standard of care for management of MVID, can cost up to $150,000 a year or more with complications. MVID patients suffer from severe cholera-like diarrhea, and symptomatic management of diarrhea in MVID may reduce their dependence on PN. We plan to host an investor-facing webinar in the near future with leading pediatric gastroenterologists to further elaborate the value of managing diarrhea in MVID patients with intestinal failure."

Crofelemer has been granted Orphan Drug Designation (ODD) by the FDA and the European Medicines Agency (EMA) for MVID. The ODD program in both the US and European Union qualifies sponsors to receive potential incentives to develop therapies for the diagnosis, prevention, or treatment of rare diseases or conditions. Crofelemer has also been granted ODD by the FDA and the EMA for short bowel syndrome (SBS). SBS patients with intestinal failure are also treated with PN. Jaguar is supporting investigator-initiated proof-of-concept studies of crofelemer for SBS with intestinal failure and MVID in the EU 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.

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 *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 S.p.A

Napo Pharmaceuticals, a Jaguar Health company, focuses on developing and commercializing proprietary 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. 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 an investor-facing webinar will be held in the near future with leading pediatric gastroenterologists to further elaborate the value of managing diarrhea in MVID patients with intestinal failure, and the expectation that published data from proof-of-concept studies could support reimbursed early patient access to crofelemer for SBS or MVID with intestinal failure, 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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