



Jaguar Health Subsidiary Announces Completion of Additional Preclinical Study of Lechlemer (NP-300), the Company's Human Drug Product Candidate for Diarrhea Relief from Cholera and Other Acute Infectious Diarrhea

August 17, 2021

In support of planned Investigational New Drug application for lechlemer, Napo Pharmaceuticals, Jaguar's wholly owned subsidiary, received comprehensive animal toxicity preclinical services supported by the National Institute of Allergy and Infectious Diseases for four studies

SAN FRANCISCO, CA / ACCESSWIRE / August 17, 2021 / Napo Pharmaceuticals, Inc. ("Napo"), the wholly-owned subsidiary of Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company"), announced today the completion of an additional preclinical toxicology study intended to support continued development of NP-300 (lechlemer) for the symptomatic relief of diarrhea from cholera and other infectious diarrheal conditions. The study findings support the Investigational New Drug (IND) application Napo plans to file for lechlemer for this indication in the first half of 2022.

This preclinical toxicology study was a 28-day repeated oral dose study in dogs, which augments the 28-day toxicology study in rats. Napo received preclinical services supported by the National Institute of Allergy and Infectious Diseases ("NIAID") to support development of lechlemer. NIAID is part of the National Institutes of Health. Under NIAID's suite of preclinical services, NIAID-funded contractors conducted both 28-day toxicology studies as well as the two initial 7-day toxicology studies.

"The 28-day general toxicology study in dogs is one of the studies required to file an IND application for NP-300, also known as lechlemer. The support of NIAID in performing these toxicology studies has been instrumental in advancing the lechlemer program, and we look forward to the day when lechlemer will be available to provide symptomatic relief and treatment of dehydrating diarrhea from acute infections such as that with cholera," said Michael K. Guy, DVM, PhD, Vice President of Preclinical and Nonclinical Studies at Napo Pharmaceuticals, Jaguar Health's wholly owned subsidiary.

Additional studies that are required to file the lechlemer IND are ongoing.

"We are grateful for NIAID's support to conduct these key preclinical animal toxicity studies of lechlemer," Lisa Conte, Jaguar's president and CEO, stated. "We believe lechlemer, which has a similar mechanism of action to crofelemer and is significantly less costly to produce, may prove beneficial initially for treating neglected diseases and conditions such as diarrhea from acute enteric infections - and may eventually prove beneficial for patients with other types of gastrointestinal disorders."

Cholera is an acute diarrheal illness caused by infection of the intestine with the bacterium *Vibrio cholerae*. According to the Centers for Disease Control and Prevention of the U.S. Department of Health & Human Services, an estimated 3-5 million cholera cases and more than 100,000 cholera-related deaths occur each year around the world. Approximately one in 10 of infected persons will have severe disease characterized by profuse watery diarrhea, vomiting, and leg cramps. In these people, rapid loss of body fluids leads to dehydration and shock. Without treatment, death can occur within hours. The largest cholera outbreak in recorded history recently occurred in Yemen. According to Oxfam, the number of cholera cases in Yemen in 2019 was the second largest ever recorded in a country in a single year, surpassed only by the numbers in Yemen in 2017. According to the Brookings Institution, cholera continues to spread in Yemen, with 180,000 new cases reported in the first eight months of 2020.

Lechlemer is a drug candidate which is planned to be developed under the botanical guidance of the U.S. Food and Drug Administration ("FDA"). It is a standardized and proprietary Napo Pharmaceuticals botanical drug product that is sustainably derived from the same source as crofelemer (Mytesi®): the *Croton lechleri* tree.

The Company has previously evaluated the effects of crofelemer for the symptomatic relief and treatment of dehydrating diarrhea in cholera patients at the renowned International Centre for Diarrhoeal Disease Research (ICDDR, B) in Bangladesh.

About Jaguar Health, Inc. & Napo Pharmaceuticals, Inc.

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. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals from plants harvested responsibly from rainforest areas. Our Mytesi® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy and the only oral plant-based prescription medicine approved under FDA Botanical Guidance.

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

About Mytesi®

Mytesi (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

See full Prescribing Information at [Mytesi.com](https://www.mytesi.com). Crofelemer, the active ingredient in Mytesi, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's belief that lechlemer will in the future be available to provide symptomatic relief and treatment of dehydrating diarrhea from acute infections such as that with cholera, the Company's expectation that the IND for lechlemer will be filed in the first half of 2022, and the Company's belief that lechlemer may prove beneficial initially for treating neglected diseases and conditions such as diarrhea from acute enteric infections and may eventually prove beneficial for patients with other types of gastrointestinal disorders. 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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