



Jaguar Health Subsidiary Receiving Preclinical Services from the National Institute of Allergy and Infectious Diseases for New Preclinical Study Initiated July 21, 2020 for Lechlemer Plant-based Drug Candidate for Cholera

July 22, 2020

SAN FRANCISCO, CA / ACCESSWIRE / July 22, 2020 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") announced today that the 28-day preclinical toxicology and safety study in rats began yesterday to support development of lechlemer, the second generation, plant-based anti-secretory drug candidate of Napo Pharmaceuticals ("Napo"), Jaguar's wholly owned subsidiary, for the symptomatic relief of diarrhea from cholera.

As previously announced, Napo Pharmaceuticals is receiving preclinical services from the National Institute of Allergy and Infectious Diseases ("NIAID") to support lechlemer development. Under NIAID's suite of preclinical services, NIAID-funded contractors are conducting the 28-day rat study. NIAID is part of the National Institutes of Health.

"We are grateful for NIAID's support to conduct this important 28-day toxicity and safety study in rats, which is expected to support the Investigational New Drug (IND) application we plan to file for lechlemer," stated Steven King, PhD, Jaguar's chief of sustainable supply, ethnobotanical research and IP. "As announced in October of 2019, a short-term, 7-day, preclinical toxicology study in rats to support lechlemer development for cholera has been completed. Under NIAID's suite of preclinical services, NIAID-funded contractors conducted the initial 7-day rat toxicology study, and completion of this shorter study allowed for this longer-term, 28-day, IND-enabling toxicity study."

The Company believes that lechlemer, which has the same mechanism of action as crofelemer and is significantly less costly to produce, may support efforts to receive a priority review voucher from the FDA for a cholera indication. Priority review vouchers are granted by the FDA to drug developers as an incentive to develop treatments for neglected diseases and rare pediatric diseases. Additionally, the Company believes lechlemer represents a long-term pipeline opportunity as a second-generation anti-secretory agent, on a global basis, for multiple gastrointestinal diseases - especially in resource-constrained countries where cost of goods is a factor, in part, because requirements often exist in such regions for drug prices to decrease annually.

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. The infection is often mild or without symptoms, but can sometimes be severe. 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 is currently occurring 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.

Lechlemer is a drug candidate under the botanical guidance of the U.S. Food and Drug Administration ("FDA"). It is a standardized and proprietary Napo botanical extract that is distinct from Mytesi[®] (crofelemer), the Company's FDA-approved drug product. Lechlemer is sustainably derived from the same source as Mytesi: the *Croton lechleri* tree.

The Company has previously presented Phase 2 data on crofelemer for the treatment of devastating dehydration in cholera patients from the renowned International Centre for Diarrhoeal Disease Research (icddr,b) in Bangladesh. Napo plans to follow the same study design for lechlemer.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, sustainably derived gastrointestinal products on a global basis. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in 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, 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. 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 the preclinical 28-day toxicity and safety study in rats will support the IND application the Company plans to file for lechlemer, the expectation that lechlemer may support efforts to receive a priority review voucher from the FDA for a cholera indication, the Company's belief that lechlemer represents a long-term pipeline opportunity as a second-generation anti-secretory agent, on a global basis, for multiple gastrointestinal diseases - especially in resource-constrained countries where cost of goods is a factor, and statements regarding Napo's plans for the study design for lechlemer. 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.

Contact:

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

SOURCE: Jaguar Health, Inc.

accesswire.com

<https://www.accesswire.com/598384/Jaguar-Health-Subsidiary-Receiving-Preclinical-Services-from-the-National-Institute-of-Allergy-and-Infectious-Diseases-for-New-Preclinical-Study-Initiated-July-21-2020-for-Lechlemer-Plant-based-Drug-Candidate-for-Cholera>