

# Jaguar Health Subsidiary Receiving Preclinical Services Funded by the National Institute of Allergy and Infectious Diseases in Support of Development of Lechlemer Drug Product Candidate for Cholera Indication

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SAN FRANCISCO, CA / ACCESSWIRE / June 11, 2019 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company"), a commercial stage pharmaceutical company focused on developing novel, sustainably derived gastrointestinal products on a global basis, announced today that Jaguar's wholly-owned human-health subsidiary, Napo Pharmaceuticals, Inc. ("Napo"), will receive preclinical services from the National Institute of Allergy and Infectious Diseases ("NIAID") to support the development of lechlemer, Napo's drug product candidate for a cholera indication.

Under NIAID's suite of preclinical services, NIAID-funded contractors will conduct toxicology testing for 7-day rat and dog studies. NIAID is part of the National Institutes of Health.

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<sup>®</sup> (crofelemer), the Company's FDA-approved drug product. Lechlemer is sustainably derived from the same source as Mytesi: the *Croton lechleri* tree.

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. At this time, the largest cholera outbreak in recorded history is occurring in Yemen.

"We are grateful for NIAID's support to conduct these preclinical animal studies of lechlemer," Lisa Conte, Jaguar's president and CEO, stated. "We believe 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, we believe 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."

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, sustainably derived gastrointestinal products on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas. Our Mytesi<sup>®</sup> (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

For more information about Jaguar, please visit <u>jaguar, health</u>. For more information about Napo, visit <u>napopharma.com</u>.

#### 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 expectation that the Company will utilize preclinical services from the National Institute of Allergy and Infectious Diseases, the expectation that lechlemer may support efforts to receive a priority review voucher from the FDA for a cholera indication, the belief that lechlemer represents a long-term pipeline opportunity as a second-generation anti-secretory agent, on a global basis, for multiple gastrointestinal diseases, and statements regarding 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.

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