

# Jaguar Health Announces Completion of Pilot Study in Dogs in Support of Future Clinical Investigations Evaluating Crofelemer for Treatment of Noninfectious Diarrhea in Human Cancer Patients Receiving Tyrosine Kinase Inhibitors

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SAN FRANCISCO, CA / ACCESSWIRE / June 18, 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 a nonclinical pilot study to evaluate the severity of diarrhea caused by a specified dose of a specific tyrosine kinase inhibitor (TKI) in healthy dogs has been completed. A primary nonclinical study, expected to begin this July, will evaluate the effects of crofelemer on diarrhea induced in healthy dogs by the same TKI. Both studies, which are being funded by a third-party cancer agent manufacturer, are intended to provide additional scientific rationale and support for the use of crofelemer in providing symptomatic relief of noninfectious diarrhea in human patients receiving TKI-and/or-other targeted cancer therapy containing regimens in future human clinical investigations.

Crofelemer is the active pharmaceutical ingredient in Mytesi<sup>®</sup>, Jaguar's FDA-approved drug product indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). As previously announced, crofelemer is in development for the symptomatic relief of cancer therapy-related diarrhea (CTD). A significant proportion of patients undergoing cancer therapy experience diarrhea. Novel targeted cancer therapy agents, such as epidermal growth factor receptor antibodies and TKIs, with or without cycle chemotherapy agents, may activate intestinal chloride secretory pathways, leading to increased chloride secretion into the gut lumen, coupled with significant loss of water, that would result in secretory diarrhea.

The nonclinical pilot study involved healthy Beagle dogs, which were given a once-daily administration of the specific TKI for 14 days. The pilot study allowed determination about whether the TKI dose needs to be modified in the primary study to achieve moderate-to-severe diarrhea but not very severe diarrhea that would mandate multiple dose interruptions or drug holidays. The primary study will compare three treatment groups of dogs randomized to receive crofelemer with the same TKI over a 28-day treatment period.

## 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 jaguar, health. For more information about Napo, visit 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 expectation that a primary nonclinical study will begin this July to evaluate the effects of crofelemer on diarrhea induced in healthy dogs, and statements regarding future human clinical investigations to evaluate the use of crofelemer in providing symptomatic relief of noninfectious diarrhea in human patients receiving TKI-and/or-other targeted cancer therapy containing regimens. 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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