Jaguar Health Submits Final Major Regulatory Filing for Approval of Canalevia (Crofelemer) to Treat Exercise-induced Diarrhea in Dogs

July 2, 2020

Canalevia would be first and only FDA-approved plant-based medicine for working dogs that suffer from diarrhea

SAN FRANCISCO, CA / ACCESSWIRE / July 2, 2020 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") announced today that it has submitted to the U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM) the final major regulatory filing to support approval of its oral plant-based drug candidate Canalevia ™ (crofelemer delayed-release tablets) to treat exercise-induced diarrhea (EID) in dogs.

Working dogs, including search and rescue, military and sled dogs, often suffer diarrhea as a result of engaging in long periods of intense, off-leash exercise. "Elite athletes of all species tend to have more diarrhea than their healthy but more sedentary counterparts, which can interfere with peak physical performance," said Dr. Michael Davis, DVM, Ph.D., DACVIM, DACVSMR, a veterinary physiologist and board-certified specialist in veterinary internal medicine and veterinary sports medicine at Oklahoma State University, where he conducts research on animal exercise physiology and performance.

"There is a significant need in the world of working dogs for a safe and effective medicine that can reduce the incidence and severity of exercise-induced diarrhea without affecting performance," he said.

In addition to EID, Jaguar is also seeking conditional approval to market Canalevia for chemotherapy-induced diarrhea (CID) in dogs. "We are leveraging many of the same major technical sections from our CID submission for the proposed EID indication," said Dr. Michael Guy, DVM, Ph.D., Jaguar's vice president of preclinical and nonclinical studies. "We expect that Canalevia could be available under conditional approval to treat both CID and EID in the first half of 2021."

"We're one step closer to introducing our first FDA-approved oral plant-based medicine for animals," said Jaguar president and chief executive officer Lisa Conte. "We believe Canalevia will be an important treatment option for working dogs experiencing EID as well as for the estimated 50,000 dogs that suffer from CID each year. And once CID is under control, dogs may better tolerate their chemotherapy."

"We're also excited about the potential to develop crofelemer to treat cancer therapy-related diarrhea in humans. Dogs undergoing chemotherapy are an important predictive model for crofelemer's mechanism of action in humans experiencing diarrhea as a result of cancer treatment," said Conte.

Jaguar's wholly owned subsidiary, Napo Pharmaceuticals, Inc. ("Napo"), currently markets another form of crofelemer, Mytesi®, the only non-opioid oral plant-based medicine approved by the FDA for the treatment of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. Crofelemer comes from the *Croton lechleri* tree, which is responsibly and sustainably harvested in South America.

The filing to support approval of Canalevia to treat EID in dogs consists of the Reasonable Expectation of Effectiveness technical section for Jaguar's application for conditional approval of Canalevia for EID under the Minor Use/Minor Species (MU/MS) section of The Minor Use and Minor Species Animal Health Act of 2004.

As previously announced, the CVM has confirmed the completeness of Jaguar's Reasonable Expectation of Effectiveness technical section for CID under MU/MS, as well as the CMC (Chemistry, Manufacturing and Controls) and Environmental Impact technical sections of the Company's applications for conditional approval of Canalevia for both CID and EID.

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 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 Canalevia could be available under conditional approval for EID and CID in the first half of 2021. 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. Some of the factors that could affect our actual results are included in the periodic reports on Form 10-K and Form 10-Q that we file with the Securities and Exchange Commission. 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.