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

May 28, 2020

Canalevia would be first and only FDA-approved plant-based medicine for 50,000-plus dogs that suffer from diarrhea during chemotherapy

SAN FRANCISCO, CA / ACCESSWIRE / May 28, 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) what the Company expects is the final major regulatory filing to support approval of its oral plant-based drug candidate Canalevia ™ (crofelemer delayed-release tablets) to treat chemotherapy-induced diarrhea (CID) in dogs.

According to current estimates, more than 230,000 dogs in the U.S. receive chemotherapy treatment for various cancers each year, and roughly one in four will experience diarrhea as a side effect of treatment. There currently is no FDA-approved anti-secretory prescription product to manage this debilitating diarrhea in dogs.

The filing consists of an updated version of the Target Animal Safety technical section of Jaguar's application for conditional approval of Canalevia for CID under the Minor Use/Minor Species (MU/MS) section of The Minor Use and Minor Species Animal Health Act of 2004.

"With this filing, which includes new administrative details, we are confident that CVM will deem our Target Animal Safety technical section Complete," said Dr. Michael Guy, DVM, Ph.D., Jaguar's vice president of preclinical and nonclinical studies.

As previously announced, the technical section contains data from a 2017 safety study indicating that the NOAEL (no-observed-adverse-effect level) of Canalevia in dogs is approximately six times greater than previously demonstrated, and that Canalevia also is safe for use in puppies as young as 12 weeks of age.

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

"Jaguar is now one important step closer to having our first approved medicine for use in animals," said Jaguar president and chief executive officer Lisa Conte. "We believe Canalevia will be an important treatment option for the 50,000 dogs that suffer from CID each year. And once CID is under control, dogs may better tolerate their chemotherapy."

Jaguar's wholly owned subsidiary, Napo Pharmaceuticals, Inc. ("Napo"), currently markets Mytesi®, another form of crofelemer, 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.

Napo is pursuing the development of Mytesi to treat cancer therapy-related diarrhea in humans. Conte said that dogs undergoing chemotherapy are an important predictive model for crofelemer's mechanism of action in humans experiencing diarrhea as a result of their cancer treatment.

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, 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® (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 the updated version of the Target Animal Safety technical section of the Company's application for conditional approval of Canalevia for CID will be the final major regulatory filing in the Company's effort to gain approval to market Canalevia for CID in dogs, the expectation that CVM will determine that the updated version of the Target Animal Safety technical section is Compete, the expectation that Canalevia could be available under conditional approval for CID and EID in first half of 2021, and the belief that Canalevia will be an important treatment option for the 50,000 dogs that suffer from CID each year. 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.

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