FDA Invites Jaguar Health to Expedite Submission of Regulatory Filing for Approval of Canalevia (Crofelemer) to Treat Chemotherapy-induced Diarrhea in Dogs

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

SAN FRANCISCO, CA / ACCESSWIRE / July 20, 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 second-to-last required technical section to support approval of Jaguar's oral plant-based drug candidate Canalevia ™ (crofelemer delayed-release tablets) to treat chemotherapy-induced diarrhea (CID) in dogs. Although this filing was originally scheduled for submission by the end of August 2020, the CVM recently requested that the Company expedite the filing.

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 (more than 50,000 dogs) will experience diarrhea as a side effect of treatment. There currently is no FDA-approved anti-secretory prescription product to manage this type of debilitating diarrhea in dogs.

The filing consists of the All Other Information (AOI) 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.

"We're very pleased with the request from the CVM to expedite the submission of the AOI section of our application," said Dr. Michael Guy, DVM, Ph.D., Jaguar's vice president of preclinical and nonclinical studies. "The AOI section is one of two 'minor' technical sections required as part of this application. The other minor technical section, the Labeling section, is the last of the six technical sections we need to file for the proposed CID indication, and this filing is expected to occur by the end of August 2020."

"Jaguar is now another 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 dogs that suffer from CID. And once CID is under control, dogs may better tolerate their chemotherapy."

In addition to pursuing an indication for CID in dogs, Jaguar is also seeking conditional approval to market Canalevia for exercise-induced diarrhea (EID) in dogs. "We expect that Canalevia could be available under conditional approval to treat both CID and EID in the first half of 2021," said Dr. Guy.

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. Napo is pursuing the development of Mytesi to treat cancer therapy-related diarrhea in humans.

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 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 expectation that filing of the Labeling technical section of the Company's application for conditional approval of Canalevia for CID will occur by the end of August 2020, the belief that Canalevia will be an important treatment option for the 50,000 dogs that suffer from CID each year, and the expectation that Canalevia could be available under conditional approval for CID and EID in 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.

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