Jaguar Health Clears Key Regulatory Hurdle on Path to 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 50,000-plus dogs that suffer from diarrhea annually while undergoing chemotherapy

SAN FRANCISCO, CA / ACCESSWIRE / April 1, 2020 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") announced today that it has cleared a key regulatory hurdle in the Company's effort to gain U.S. Food and Drug Administration approval to market Canalevia ™ (crofelemer delayed-release tablets) for the treatment of chemotherapy-induced diarrhea ("CID") in dogs.

Jaguar has been informed by the FDA's Center for Veterinary Medicine ("CVM") that the CMC technical section, which covers the methods and controls Jaguar has in place for manufacturing, processing, and packaging of Canalevia, has been deemed Complete as part of the Company'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. The MU/MS designation is modeled on the orphan-drug designation for human drug development.

According to the Company's current estimates, more than 230,000 dogs receive chemotherapy treatment for various cancers each year in the U.S., 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.

Crofelemer, Canalevia's active ingredient, comes from the *Croton lechleri* tree, which is responsibly and sustainably harvested in South America. Canalevia, which is the first and only oral plant-based product candidate for CID in dogs, acts locally in the gut and does not interact with chemotherapy drugs.

"With FDA's confirmation that the CMC section of our application is complete, Jaguar is one step closer to receiving our first approved medicine indicated for animal use," said Jaguar president and chief executive officer Lisa Conte. "We understand the deep bond between people and their dogs, and we are excited to move one step closer to bringing this important treatment option to dogs to alleviate CID, which may also help them 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. Napo is pursuing development of cancer therapy-related diarrhea as a potential follow-on indication for Mytesi.

"We believe dogs undergoing chemotherapy are an important predictive model for Mytesi's mechanism of action in human patients suffering from CID," Conte said.

In addition to confirming the completeness of Jaguar's CMC (Chemistry, Manufacturing and Controls) technical section, the CVM, as previously announced, has confirmed the completeness of two of the other three major technical sections of Jaguar's application for Canalevia.

"Upon receiving conditional approval, when CVM indicates that the final technical section is complete, we will be prepared to launch Canalevia for CID," said Dr. Michael Guy, DVM, MS, PhD, Jaguar's vice president of preclinical and nonclinical studies. "We expect this launch to occur in the first quarter of 2021."

In addition to CID, Jaguar also is seeking conditional approval from CVM to market Canalevia for exercise-induced diarrhea (EID) in dogs under MU/MS. Jaguar will leverage many of the same major technical sections for EID that were submitted for the CID indication.

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, if Canalevia receives conditional approval for the indication of CID in dogs, Jaguar will conduct the commercial launch of Canalevia for CID in dogs in the first quarter of 2021, the belief that dogs undergoing chemotherapy are an important predictive model for Mytesi's mechanism of action in human patients suffering from CID, and the Company's plans to leverage use of many of the same major technical sections for EID that have been submitted in support of the Company's application for Canalevia for the indication of CID in dogs. 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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