Jaguar Health Clears Important Hurdle on Path to Approval of Canalevia (Crofelemer) to Treat Exercise-Induced Diarrhea (EID) in Dogs

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- ***Canalevia is the first and only oral plant-based prescription drug candidate for EID in dogs***
- ***Diarrhea is a common problem among working dogs subjected to intense, long-duration off-leash exercise***

SAN FRANCISCO, CA / ACCESSWIRE / May 12, 2020 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") announced today that it has cleared an important regulatory hurdle in the Company's effort to gain U.S. Food and Drug Administration approval to market Canalevia ™ (crofelemer delayed-release tablets), the Company's oral plant-based prescription drug candidate, for the treatment of exercise-induced diarrhea (EID) in dogs.

Jaguar has been informed by the FDA's Center for Veterinary Medicine (CVM) that the Environmental Impact technical section has been deemed Complete as part of the Company'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. This section provides an assessment of a drug's potential direct and indirect effect on the environment.

Working dogs - such as sled dogs and military 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, and while diarrhea may not be life-threatening, it is significant if the goal is 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 product that can reduce the incidence and severity of exercise-induced diarrhea without affecting performance," he said.

In addition to EID, Jaguar also is seeking conditional approval from CVM to market Canalevia for cancer-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, MS, PhD, Jaguar's vice president of preclinical and nonclinical studies. "If we are successful, Canalevia could be available under conditional approval for EID or CID in first half of 2021."

In addition to confirming the completeness of Jaguar's Environmental Impact technical section for EID, the CVM previously confirmed the completeness of the CMC (Chemistry, Manufacturing and Controls) technical section of the Company's applications for conditional approval of Canalevia for both EID and CID under MU/MS. As previously announced, the CVM has also confirmed the completeness of two of the other three major technical sections of Jaguar's application for Canalevia for CID.

Crofelemer, Canalevia's active ingredient, comes from the *Croton lechleri* tree, which is responsibly and sustainably harvested in South America. 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.

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 Canalevia could be available under conditional approval for EID or CID 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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