Jaguar Health Completes Final Regulatory Filing for Conditional New Animal Drug Approval of Canalevia (Crofelemer) to Treat Exercise-induced Diarrhea (EID) in Dogs

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Canalevia® Would Be the First and Only Treatment for EID in Dogs To Receive Any Type of Approval From FDA

SAN FRANCISCO, CA / ACCESSWIRE / May 3, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX), under its Jaguar Animal Health tradename for the veterinary market, today announced that it has completed filing of the final regulatory section with the U.S. Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) to support conditional new animal drug approval of the company's oral plant-based drug candidate Canalevia (crofelemer delayed-release tablets) to treat exercise-induced diarrhea (EID) in dogs.

In December of 2021, Jaguar Animal Health received conditional approval from the FDA for Canalevia®-CA1 for chemotherapy-induced diarrhea (CID) in dogs. Conditional approval is an FDA drug approval pathway for animal products under The Minor Use and Minor Species (MUMS) Animal Health Act of 2004.

"We leveraged many of the same technical sections from our successful CID submission for the proposed EID indication," said Michael Guy, DVM, MS, Ph.D., Jaguar Health's vice president of preclinical and nonclinical studies. "We expect that Canalevia could receive FDA conditional approval, under the name Canalevia®-CA2, to treat EID in dogs in the fourth quarter of 2022."

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 though more sedentary counterparts, which can interfere with peak physical performance," said 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."

As previously announced, the CVM has already confirmed the completeness of three of the four major required technical sections of Jaguar Animal Health's application for conditional approval of Canalevia for EID.

About Jaguar Health, Jaguar Animal Health, Napo Pharmaceuticals, & Napo Therapeutics

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Animal Health is a tradename of Jaguar Health. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human pharmaceuticals from plants harvested responsibly from 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. Our crofelemer drug product candidate is the subject of the **OnTarget** study, an ongoing pivotal Phase 3 clinical trial for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.), an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe.

For more information about Jaguar Health, please visit https://jaguar.health. For more information about Napo Pharmaceuticals, 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.

About The Minor Use and Minor Species (MUMS) Animal Health Act of 2004

MUMS designation is modeled on the orphan-drug designation for human drug development and offers possible financial incentives to encourage MUMS drug development, such as the availability of grants to help with the cost of developing the MUMS drug and a longer period of marketing exclusivity. The purpose of the MUMS Act is to encourage development and availability of animal drugs intended as a minor use in a major species (dogs, cats, cattle, horses, chickens, turkeys, and pigs) to treat diseases which occur infrequently or in limited geographic areas, and to encourage development and availability of animal drugs for use in minor species (defined as all animals other than humans that are not one of the seven major species).

FDA has established a "small number" threshold for minor use in each of the seven major species covered by the MUMS act. The small number threshold is currently 70,000 for dogs, representing the largest number of dogs that can be affected by a disease or condition over the course of a year and still have the use qualify as a minor use.

Canalevia-CA1 has received MUMS designation for CID in dogs, and Jaguar Health believes Canalevia meets the requirements for MUMS designation for the planned EID indication in dogs.

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 in the fourth quarter of 2022, and Jaguar Health's belief that Canalevia meets the requirements for MUMS designation for the planned EID indication 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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