Jaguar Health Provides Updates on Canalevia (Crofelemer), the First Plant-based Prescription Medicine Under Development for Chemotherapy-induced Diarrhea in Dogs and Exercise-induced Diarrhea in Dogs

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

Canalevia will be available by fourth quarter 2021, if conditionally approved

SAN FRANCISCO, CA / ACCESSWIRE / May 18, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") today provided updates regarding the development program for the Company's oral plant-based drug candidate Canalevia ™ (crofelemer delayed-release tablets) to treat chemotherapy-induced diarrhea (CID) in dogs and exercise-induced diarrhea (EID) in dogs. There currently is no FDA-approved anti-secretory prescription product to manage these types of debilitating diarrhea in dogs.

"We are pleased to report our progress on Canalevia, which has the potential to help thousands of dogs experiencing diarrhea due to chemotherapy," said Michael Guy, DVM, Ph.D., Jaguar's vice president of preclinical and nonclinical studies. "With feedback from the FDA's Center for Veterinary Medicine (CVM), we've completed the submission of updated versions of required minor and major technical sections of Jaguar's application for conditional approval of Canalevia for CID under The Minor Use and Minor Species (MUMS) Animal Health Act of 2004. We are planning for the expected regulatory approval and commercialization of Canalevia under conditional approval for CID in the fourth quarter of 2021."

"Management of this type of debilitating diarrhea in dogs undergoing cancer treatment is a comfort issue for dogs. Additionally, diarrhea management may also help dogs better tolerate their chemotherapy and improve the home and living environment for dog owners," said Lisa Conte, Jaguar's president and chief executive officer and parent of two Jack Russell Terriers. "We are excited to report our progress on this first-of-its-kind medicine and believe Canalevia will be an important treatment option for veterinary healthcare teams and dog owners once approved."

The Company is also in the process of completing the submission package for EID for regulatory approval and commercialization in the same time frame. 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 but more sedentary counterparts, which can interfere with 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 safe and effective medicine that can reduce the incidence and severity of exercise-induced diarrhea without affecting performance."

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. Jaguar estimates that 5,000 to 15,000 dogs in the U.S. experience EID annually.

Jaguar's wholly owned subsidiary, Napo Pharmaceuticals, Inc., currently markets a form of crofelemer, Mytesi®, which is 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, derived from the *Croton lechleri* tree, 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, Jaguar has received Minor Use/Minor Species (MUMS) Designation for Canalevia for CID in dogs. Jaguar will also be applying for MUMS Designation for Canalevia by the end of May 2021 to treat EID in dogs. To obtain conditional approval of a MUMS drug, a company must submit Chemistry, Manufacturing and Controls (CMC), Environmental Impact, and Target Animal Safety data identical to that required for a new animal drug application (NADA) as well as data suggesting a reasonable expectation of effectiveness (RxE). After the submission and the review of the application, the FDA through the CVM can then grant a conditional approval (CA-1). This approval allows for commercialization of the product while the sponsor continues to collect the substantial evidence of effectiveness required for a full NADA approval. A sponsor that gains approval or conditional approval for a MUMS-designated drug then receives seven years of marketing exclusivity.

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 (defined as 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).

About Jaguar Health, Inc. and Napo Pharmaceuticals, Inc.
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, specifically chronic, debilitating diarrhea. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal 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.

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 belief that Canalevia has the potential to help thousands of dogs experiencing diarrhea due to chemotherapy, the belief that diarrhea management in dogs undergoing cancer treatment may help dogs better tolerate their chemotherapy and improve the home and living environment for dog owners, the belief that Canalevia will be an important treatment option for veterinary healthcare teams and dog owners once approved, and the expectation that Canalevia could be available under conditional approval for CID and EID in the fourth quarter 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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