Jaguar Health Announces Key Finding for Final Canalevia Technical Section for Proposed Indication of Chemotherapy-Induced Diarrhea in Dogs

June 19, 2019

Target Animal Safety Study Results Indicate Canalevia ™ NOAEL (No-Observed-Adverse-Effect Level) is Approximately Six Times Greater than Previously Demonstrated and that Canalevia is Also Safe for Use in Puppies

SAN FRANCISCO, CA / ACCESSWIRE / June 19, 2019 / Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company"), a commercial stage pharmaceutical company focused on developing novel, sustainably derived gastrointestinal products on a global basis, announced today that the Target Animal Safety Technical Section of the Company's application for conditional approval of Canalevia ™ for chemotherapy-induced diarrhea (CID) in dogs is expected to be submitted to the U.S. Food & Drug Administration's Center for Veterinary Medicine (CVM) in the third quarter of 2019. This Technical Section, which is the last of the four Technical Sections Jaguar is required to file for Canalevia for the proposed CID indication, will contain data from a 2017 target animal safety study indicating that the NOAEL (no-observed-adverse-effect level) of Canalevia in dogs is approximately six times greater than previously demonstrated, and that Canalevia is also safe for use in puppies.

Canalevia, Jaguar's lead veterinary drug product candidate, is a canine-specific oral formulation of crofelemer, an active pharmaceutical ingredient (API) isolated and purified from the *Croton lechleri* tree, which is sustainably harvested.

The safety of residues of veterinary drugs is most commonly addressed through the conduct of target animal safety studies that provide for the determination of the NOAEL.

The 2017 toxicology study is the first study to demonstrate the safety of Canalevia in puppies as young as 12 weeks of age. Prior crofelemer toxicology studies only involved adult dogs.

As previously announced, Jaguar has received Minor Use/Minor Species (MUMS) designation, per the requirements of The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act), for Canalevia for CID 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. 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.

"I'm pleased to say that completion of the pharmacokinetics analysis of the blood samples from the target animal safety study is the last step remaining in getting the Safety Technical Section ready to submit to CVM," Dr. Michael Guy, DVM, MS, PhD, Jaguar's vice president and clinical veterinarian, commented. "With receipt of conditional approval for this indication, we expect to conduct the commercial launch of Canalevia for CID in dogs in the first half of 2020."

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).

"Since our July 2017 merger with Napo Pharmaceuticals, as previously announced, Jaguar's human portfolio has been, and continues to be, our core focus. However, CID is an interesting model for human medical need and is being pursued as our first prescription indication for animal health," Lisa Conte, Jaguar's president and CEO, stated. "We believe there is an important unmet medical need for the treatment of CID in dogs. Certain cancer treatment agents provided to dogs are human drugs, or have the same mechanism of action as human cancer drugs, and these agents and mechanisms of action often have meaningful rates of diarrhea in humans as well. Canalevia acts locally in the gut and is minimally absorbed systemically. It does not alter gastrointestinal motility, has no significant effects on normally-functioning intestinal ion channels or the transport of electrolytes or fluids, and has no side effects different from placebo. These features are further augmented by the lack of effects of Canalevia on the absorption and/or metabolism of co-administered chemotherapy drugs, orally or by other routes of administration. Canalevia acts by normalizing the flow of excess ions and water in the intestinal lumen. The flow of excess ions and water into the intestinal lumen is the last step common to the manifestation of secretory diarrhea."

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 the Company will file the Canalevia Target Animal Safety Technical Section with CVM in the third quarter of this year, 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 half of 2020, and the belief that there is an important unmet medical need for the treatment 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. 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.

CONTACT:

Peter Hodge
Jaguar Health, Inc.
phodge@jaguar.health
Jaguar-JAGX

SOURCE: Jaguar Health, Inc.