



## **FDA Indicates that Jaguar's Reasonable Expectation of Effectiveness Technical Section is Complete for Use of Canalevia for Treatment of Chemotherapy-Induced Diarrhea in Dogs**

March 8, 2018

**SAN FRANCISCO, CA / ACCESSWIRE / March 8, 2018** / Jaguar Health, Inc. (NASDAQ: JAGX) (Jaguar or the Company), a commercial stage natural-products pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products on a global basis, announced today that the U.S. Food & Drug Administration's Center for Veterinary Medicine (CVM) has indicated that the Company's Reasonable Expectation of Effectiveness (RxE) Technical Section is complete towards conditional approval of Canalevia™ (crofelemer delayed-release tablets) for treatment of chemotherapy-induced diarrhea (CID) in dogs, based on CVM's review of the results of Jaguar's completed pilot study (CANA-001) of Canalevia™ for this indication.

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.

As previously announced, Jaguar has received Minor Use in a 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 Environmental Impact (EI), Chemistry, Manufacturing, and Controls (CMC) 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.

"Jaguar has now completed two of the four required technical sections of the Company's application for conditional approval of Canalevia™ for CID in dogs. With receipt of conditional approval for this indication, we would expect to conduct the commercial launch of Canalevia™ for CID in dogs in mid-2019," Dr. Michael Guy, DVM, MS, PhD, Jaguar's vice president and clinical veterinarian, commented.

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 product performance and is being pursued as our first prescription indication for animal health. We believe there is an important unmet medical need for the treatment of CID in dogs," Lisa Conte, Jaguar's president and CEO, stated, "and that Canalevia™ is an ideal treatment for CID in dogs because of its demonstrated novel anti-secretory mechanism of action. 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."

As also previously announced, CVM has indicated that the use of Canalevia™ for the treatment of exercise-induced diarrhea (EID) in dogs qualifies as a minor use, which means Canalevia™ is also eligible for conditional approval for the indication of EID in dogs. If Canalevia™ receives conditional approval for this second indication, the Company currently expects to conduct the commercial launch of Canalevia™ for EID in dogs in mid-2019 as well.

### **About Jaguar Health, Inc.**

Jaguar Health, Inc. is a commercial stage natural-products 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](http://jaguar.health). For more information about Napo, visit [napopharma.com](http://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%).

More information and complete Prescribing Information are available at [Mytesi.com](http://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 mid-2019, the belief that there is an important unmet medical need for the treatment of CID in dogs and that Canalevia™ is an ideal treatment for CID in dogs, and that, if Canalevia™ receives conditional approval for the indication of EID in dogs, Jaguar will conduct the commercial launch of Canalevia™ for EID in dogs in mid-2019. 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.

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**SOURCE:** Jaguar Health, Inc.