FDA Indicates That Jaguar's Canalevia Drug Product Candidate Qualifies as "Minor Use" for Exercise-Induced Diarrhea (EID) in Dogs, Rendering Canalevia Eligible for Conditional Approval for This Indication

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Jaguar Expects to Conduct the Commercial Launch of Canalevia in the First Half of 2018 for EID and CID (Chemotherapy-Induced Diarrhea) in Dogs, Dependent on Receiving Conditional Approval for These Indications

SAN FRANCISCO--(BUSINESS WIRE)--Sep. 20, 2017-- Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar), a natural-products pharmaceuticals company focused on developing and commercializing novel, sustainably-derived gastrointestinal products for both human prescription use and veterinary use on a global basis, announced today that the U.S. Food & Drug Administration's Center for Veterinary Medicine (CVM) has indicated that the use of Canalevia ™ for treatment of exercise-induced diarrhea (EID) in dogs qualifies as a "minor use", per the requirements of The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act), which means that Canalevia ™ is eligible for conditional approval for the indication of EID in dogs. Canalevia ™, Jaguar's lead veterinary drug product candidate, is under investigation for treatment of various types of diarrhea in dogs. EID is a distinct physiological manifestation that has been recorded in dogs, humans and horses.

"EID is a common problem among working dogs, such as sled dogs and military dogs, when subjected to periods of intense, long-duration off-leash exercise," Dr. Michael Guy, DVM, MS, PhD, Jaguar's vice president and clinical veterinarian, explained. "Several mammalian species that train for and run in competitive events can push themselves to extreme physical demands. At this highest level of physical exertion, secretory diarrhea is a common result, and the diarrhea can be debilitating enough to require medical attention and removal from competition or training. Diarrhea can have serious consequences for the canine athlete due to their high capacity for metabolic heat generation and reliance on evaporative cooling to dissipate heat."

"The best-known examples of these incredible canine athletes are those that participate in the Iditarod sled dog race—The Last Great Race—across Alaska every March. Teams of up to 16 dogs mush over 1,000 miles across Alaska in only 8-10 days, and approximately 40% of these dogs will experience severe diarrhea," commented Dr. Guy.

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). 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.

FDA established, and periodically reassesses, a specific "small number of animals" (defined as <1% of the total U.S. population of the specified species) for each of the seven major animal species in order to determine whether any particular intended use in a major species qualifies as a minor use. For dogs, this number is currently 70,000. Jaguar believes Canalevia ™ will qualify for MUMS designation for EID because, in Jaguar's estimate, the total number of dogs in the United States affected by EID on an annual basis is less than 70,000.

Jaguar has already received MUMS designation for Canalevia ™ for use in dogs with chemotherapy-induced diarrhea (CID), which provides a possible opportunity to shorten the timeframe to commercialization for the CID indication. If Canalevia ™ receives conditional approval for CID and EID in dogs, Jaguar expects to conduct the commercial launch of Canalevia ™ for both indications in the first half of 2018.

Canalevia ™ is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient (API) isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Canalevia ™ is the subject of a previously announced collaboration between Jaguar and Elanco US Inc. (Elanco), a wholly-owned subsidiary of Eli Lilly. Per the terms of the agreement between Jaguar and Elanco, the two companies will collaborate on the global development of Canalevia ™ for treatment of acute diarrhea in dogs, as well as on co-promotion and commercialization of Canalevia ™ for the proposed indication of acute diarrhea in dogs in the U.S. Jaguar has retained commercial responsibility for the proposed CID and EID indications of Canalevia ™ in dogs.

"We believe there is an important unmet medical need for the treatment of CID and EID in dogs," Lisa Conte, Jaguar's president and CEO, stated. "We believe Canalevia ™ is an ideal treatment for both indications 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. With regard to CID, 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 acute diarrhea. As a result, we believe Canalevia ™ may be effective in the treatment of acute diarrhea, regardless of cause, including CID and EID."

To obtain conditional approval of a MUMS drug, the company must submit Chemistry, Manufacturing, and Controls (CMC) and safety data similar 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 receives seven years of marketing exclusivity.

In June 2015 Jaguar completed a multi-site pilot safety study involving the anticipated commercial formulation of Canalevia ™ for both CID and EID, and Jaguar expects to complete submission of all required major technical sections for the NADA for CID and EID to the FDA for phased review by the end of next month. Jaguar expects to receive FDA acknowledgment of the completion of all required technical sections in support of conditional approval of Canalevia ™ in the first half of 2018 for CID and EID in dogs. With conditional approval under MUMS designation for Canalevia ™ for use in dogs with EID, Jaguar would be required to initiate a pivotal field study in the five years following conditional approval to generate the data required for full NADA approval.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a natural-products pharmaceuticals company focused on developing and commercializing novel, sustainably derived gastrointestinal products for both human prescription use and animals 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. Mytesi® is in development for multiple possible follow-on indications, including chemotherapy-induced diarrhea; orphan-drug indications for infants and children with congenital diarrheal disorders and short bowel syndrome; supportive care for inflammatory bowel disease (IBD); irritable bowel syndrome (IBS); and as a second-generation anti-secretory agent for use in cholera patients. Canalevia ™ is our lead animal prescription drug candidate, intended for treatment of various forms of diarrhea in dogs. Equilevia ™ is Jaguar's non-prescription product for total gut health in equine athletes. Canalevia ™ and Equilevia ™ contain ingredients isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Neonorm ™ Calf and Neonorm ™ Foal are Jaguar's lead non-prescription animal products. Mytesi ®, Canalevia ™, Equilevia ™ and Neonorm ™ are distinct products that act at the same last step in a physiological pathway generally present in mammals.

For more information about Jaguar, please visit jaguar.health. For more information about Napo, visit napopharma.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that it will conduct the commercial launch of Canalevia ™ for the indications of CID and EID in the first half of 2018, the belief that Canalevia ™ may be effective in the treatment of acute diarrhea, regardless of cause, including CID and EID, Jaguar's expectation that it will complete submission of all required major technical sections for the NADA for CID to the FDA for phased review by the end of next month, Jaguar's expectation that it will receive FDA acknowledgment of the completion of all required technical sections in support of conditional approval of Canalevia ™ in the first half of 2018 for CID and EID in dogs, and the development of potential Mytesi® follow-on indications. 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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