Jaguar Animal Health Seeks MUMS Designation for Canalevia for Exercise-Induced Diarrhea in Dogs

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SAN FRANCISCO--(BUSINESS WIRE)--Mar. 14, 2017-- Jaguar Animal Health, Inc. (NASDAQ:JAGX) (Jaguar), an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, foals, and high value horses, announced today that it has submitted a formal request to the U.S. Food & Drug Administration's Center for Veterinary Medicine (CVM) for a determination about whether or not Canalevia ™ qualifies as a "minor use", per the requirements of The Minor Use and Minor Species Animal Health Act (MUMS Act), for the indication of exercise-induced diarrhea (EID) in dogs. EID is a distinct physiological manifestation that has been recorded in dogs, humans and horses. EID may occur before, during or after sustained physical exertion.

The MUMS Act became effective in 2004. The purpose of the Act is to encourage development and availability of animal drugs intended to be used 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 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.

Canalevia ™, Jaguar's lead drug product candidate, under investigation for various types of diarrhea in dogs, is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Numerous animal and human clinical trials have shown significant beneficial results in the use of crofelemer in the treatment of secretory diarrhea.

Jaguar has already received MUMS designation for Canalevia ™ for use in dogs with Chemotherapy-Induced Diarrhea (CID), which the Company expects will be the first indication available commercially in the next year.

"If we are successful in obtaining MUMS designation for Canalevia ™ for use in dogs with EID, it is our hope that this could lead to access to Canalevia ™, under conditional approval, for dogs for this indication also within a year," commented Lisa Conte, Jaguar's president and CEO.

Dr. Michael Guy, DVM, MS, PhD, Vice President and Clinical Veterinarian of Jaguar, added, "EID is a common problem among working dogs, such as sled dogs and military dogs, when subjected to periods of intense, long-duration exercise off-leash. Several mammalian species that physically train 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 that heat."

FDA established, and periodically reassesses, a specific "small number of animals" for each of the seven major animal species to be used in determining whether any particular intended use in a major species qualifies as a minor use. For dogs, this number is currently 70,000. Jaguar believes that Canalevia ™ will qualify for MUMS designation for EID because, in the Company's estimate, the total number of dogs in the United States affected by EID on an annual basis is less than 70,000. If CVM decides that the indication of Canalevia ™ for EID is an acceptable minor use, then Jaguar will be eligible to apply for MUMS designation for this indication.

To obtain conditional approval of a MUMS drug, Jaguar must submit CMC (Chemistry, Manufacturing and Controls) and safety data similar to that required for an NADA (New Animal Drug Application), as well as data suggesting a reasonable expectation of effectiveness. After the submission and review of the application, the FDA through the CVM can 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. The sponsor of a designated MUMS drug has up to five years to demonstrate substantial evidence of effectiveness. A sponsor that gains approval or conditional approval for a MUMS designated drug receives seven years of marketing exclusivity.

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 such conditional approval to generate the data required for full NADA approval.

Canalevia ™ is the subject of a recently forged collaboration with Elanco US Inc. Jaguar and Elanco US Inc. 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 canine acute diarrhea indication in the U.S. Jaguar has retained commercial responsibility for the CID and EID indications of Canalevia ™ in dogs.

About Jaguar Animal Health, Inc.

Jaguar Animal Health, Inc. is an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, foals, and high value horses. Canalevia ™ is Jaguar's lead prescription drug product candidate, intended for the treatment of various forms of diarrhea in dogs. Equilevia ™ (formerly referred to as SB-300) is Jaguar's prescription drug product candidate for the treatment of gastrointestinal ulcers in horses. Canalevia ™ and Equilevia ™ contain ingredients isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Neonorm ™ Calf and Neonorm ™ Foal are the Company's lead non-prescription products. Neonorm ™ is a standardized botanical extract derived from the *Croton lechleri* tree. Canalevia ™ and Neonorm ™ are distinct products that act at the same last step in a physiological pathway generally present in mammals. Jaguar has nine active investigational new animal drug applications, or INADs, filed with the FDA and intends to develop species-specific formulations of Neonorm ™ in six additional target species, formulations of Equilevia ™ in horses, and Canalevia ™ for cats and dogs.

For more information, please visit www.jaguaranimalhealth.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of section 27A of the Securities Act of 1933 and section 21E of the Securities Exchange Act of 1934. These include statements regarding Jaguar's belief that Canalevia ™ for use in CID in dogs will be the first indication available commercially in the next year, the possible availability of Canalevia ™, under conditional approval, for dogs for the indication of EID in dogs within a year, Jaguar's belief that Canalevia ™ will qualify for MUMS designation for EID, Jaguar's plan to develop formulations of Equilevia ™ in horses and species-specific formulations of Neonorm ™ in additional target species, and Jaguar's plan to develop formulations of Canalevia ™ for cats and 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.

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