Jaguar Animal Health Initiates Pivotal Field Study to Evaluate Safety and Effectiveness of Canalevia Drug Product Candidate for Treatment of Acute Diarrhea in Dogs

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SAN FRANCISCO--(BUSINESS WIRE)--Dec. 22, 2015-- Jaguar Animal Health, Inc. (“Jaguar”), an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, and horses, announced today that it has initiated a pivotal clinical field study to evaluate the safety and effectiveness of Canalevia ™, the Company’s lead prescription drug product candidate for the treatment of acute diarrhea in dogs. Canalevia is a canine-specific formulation of crofelemer, a novel, first-in-class, anti-secretory active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree, which is sustainably harvested.

Crofelemer has demonstrated efficacy in numerous human clinical trials of acute watery diarrhea induced by various infectious pathogens, and a human-specific formulation of crofelemer was approved by the U.S. Food and Drug Administration in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

Jaguar’s pivotal trial is being conducted in support of the Company’s filing of a new animal drug application (NADA) for Canalevia ™ for the indication of acute diarrhea in dogs. The prospective, blinded, randomized, placebo-controlled study will be conducted on an inpatient basis at private veterinary practices, animal shelters and animal rescues across the U.S. A single protocol will be followed at all sites, and enrolled dogs will remain on-site and be individually housed for the duration of the study. The study will enroll at least 150 dogs exhibiting secretory, or watery, diarrhea. Participating dogs will be randomized to receive either Canalevia ™ or a placebo orally twice daily for three days. The study's primary endpoint will be to demonstrate a resolution of diarrhea. The study period will be divided into three 24-hour treatment periods followed by a 24-hour observation period, and fecal assessments will be completed at least six times daily. Study completion testing will include a physical examination, clinical pathology testing and a final fecal assessment.

In February 2015 Jaguar announced top-line results for its proof-of-concept study to evaluate the clinical benefits of Canalevia ™. The multicenter, randomized, double-blind, controlled study assessed the efficacy of Canalevia ™ administered orally in alleviating clinical signs associated with secretory diarrhea in dogs. Thirty-nine dogs with secretory diarrhea were evaluated in the study. The statistically significant results showed Canalevia ™ treatment to be superior to placebo in the resolution of diarrhea, measured as a percentage of drug-treated dogs (91.0%) that achieved a formed stool during the study versus placebo-treated animals (50.0%), with a p-value of 0.007.

“The design, enrollment criteria, endpoints, and powering assumptions for our pivotal Canalevia ™ study are based on our experience and success with the Canalevia ™ proof-of-concept study we completed earlier this year,” stated Lisa Conte, Jaguar’s president and CEO. “We are confident that Canalevia ™ will be a new tool in the treatment of canine acute diarrhea—and the coincident health and quality of life issues for both dogs and their owners.”

Jaguar has submitted to the FDA all required major technical sections towards a conditional NADA for Canalevia ™ for dogs suffering from chemotherapy induced diarrhea (CID), a minor use in a major species (MUMS). MUMS is an FDA drug designation, similar to the orphan drug designation in humans, which is typically limited to the use of a drug to treat disease that occurs infrequently or in a small number of animals. FDA encourages sponsors to seek MUMS designation and conditional approval of qualifying drugs to address unmet medical needs in the veterinary industry. Jaguar is preparing for the expected commercial launch of Canalevia ™ for CID in mid-2016. Canalevia ™ will be the same commercial formulation for both the CID and acute diarrhea indications.

Diarrhea is one of the most common reasons for veterinary office visits for dogs and is the second most common reason for visits to the veterinary emergency room, yet there are no FDA-approved anti-secretory agents to treat canine diarrhea. According to the American Veterinary Medical Association, there were approximately 70 million dogs in the United States in 2012. Jaguar estimates that in the U.S., veterinarians see approximately six million annual cases of acute and chronic diarrhea in dogs. Devastating dehydration can occur rapidly for the animal, and the lack of control in urban settings where owners don’t have easy access to outdoor facilities is a significant problem for families with dogs.

About Canalevia ™

Canalevia ™ is Jaguar’s lead prescription drug product candidate for the treatment of various forms of diarrhea in dogs. Canalevia ™ is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from *Croton lechleri,* a tree that is sustainably harvested and contains anti-secretory properties. The product is an oral, enteric-coated, twice daily formulation of crofelemer that is not absorbed systemically at the therapeutic dose, but acts locally in the gastrointestinal tract. It acts at the last physiological step, conserved across mammalian species, in the manifestation of acute diarrhea.

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, and horses. Canalevia ™ is Jaguar's lead prescription drug product candidate for the treatment of various forms of diarrhea in dogs. Canalevia ™ is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Neonorm ™ Calf and Neonorm ™ Foal are the Company's lead non-drug 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, and formulations of Canalevia ™ for cats, horses and dogs.

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

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's belief that Canalevia ™ will be a new tool in the treatment of canine acute diarrhea—and the coincident health and quality of life issues for both dogs and their owners, Jaguar's expected commercial launch of Canalevia ™ for CID in mid-2016, Jaguar's intention to develop species-specific formulations of Neonorm ™ in additional target species, and the Company's plan to develop formulations of Canalevia ™ for cats, horses 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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