Jaguar Completes Study in Dogs with Chemotherapy-Induced Diarrhea with Commercial Formulation of Canalevia

July 1, 2015

Jaguar Targeting First Prescription Product Launch in Early 2016

SAN FRANCISCO--(BUSINESS WIRE)--Jul. 1, 2015-- Jaguar Animal Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company"), an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, announced today that it recently completed a multi-site pilot safety study involving the anticipated commercial formulation of Canalevia ™ in dogs suffering from chemotherapy-induced diarrhea (CID).

Canalevia ™, the Company's lead prescription drug candidate, 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. Numerous animal and human clinical trials have shown significant beneficial results in the use of crofelemer in the treatment of acute watery diarrhea induced by various infectious pathogens. A human-specific formulation of crofelemer was approved by the U.S. Food and Drug Administration (FDA) in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

The objective of the multi-site study was to determine the safety and tolerability of enteric-coated crofelemer tablets in dogs with CID when administered orally twice daily for six treatments at the recommended dose range of 2-4mg/kg. The eight dogs that participated in the study were enrolled based on current or historical episodes of diarrhea correlating to chemotherapy treatment. The study was a safety assessment as requested by the FDA's Center for Veterinary Medicine (CVM), and diarrhea or unformed stool consistency was not an eligibility criteria. However, 25% of the dogs entered the study with unformed stools and responded during the treatment with formed or amorphous stools or no stool. None of the remaining patients progressed to unformed stools.

Jaguar initiated a rolling New Animal Drug Application (NADA) with the CVM at the end of 2014, and the recent safety study is expected to be the final animal study requirement for completing this application. The Company is pursuing a Minor Use, Minor Species (MUMS) approval from the CVM for Canalevia ™ for CID in dogs to shorten the timeframe to commercialization. Members of Jaguar's development team met recently with the CVM regarding the MUMS regulatory pathway, and, if the Company receives conditional approval from the CVM for an indication for CID, Jaguar expects to launch Canalevia ™ for CID in dogs by early 2016.

The Company completed a canine proof-of-concept study in February 2015, with statistically significant results, in support of protocol concurrence discussions with the CVM regarding expansion of labeled indications of watery diarrhea beyond CID to include general watery diarrhea. With conditional approval under MUMS designation for Canalevia ™ for CID in dogs, 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. Jaguar expects to meet this requirement with data generated from its ongoing clinical development program for the expanded indication of general watery diarrhea in dogs.

"We are moving forward with the MUMS pathway for Canalevia ™ for CID in dogs to complement our general watery diarrhea development plan in order to make this treatment and potential relief available to suffering patients as soon as possible. As we saw anecdotally in this study, patients and their owners respond quite favorably to this new tool to manage the dehydration and discomfort of dogs undergoing chemotherapy. We are excited and grateful to have this opportunity to bring this new product, with its novel mechanism of action for the management of diarrhea, to the companion animal veterinary community," explained Jaguar's CEO Lisa Conte.

"There is currently no FDA-approved anti-secretory product to treat CID in dogs, creating a significant unmet medical need for a viable therapy. Severe diarrhea is a frequent side effect of the most commonly administered chemotherapy drugs, and we estimate that more than 230,000 dogs receive chemotherapy treatment for cancer each year in the United States, with over 25% suffering from CID," stated Ian Parker, Jaguar's Vice President of Commercial Operations.

About Canalevia ™

Canalevia ™ is Jaguar's lead prescription drug product candidate for the treatment of various forms of watery diarrhea in dogs. Canalevia ™ is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree that is sustainably harvested and contains anti-secretory properties. The product is an oral, enteric-coated, twice daily formulation of crofelemer that Jaguar is developing for the treatment of chemotherapy-induced diarrhea, or CID, in dogs. The product 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 watery 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. Canalevia ™ is Jaguar's lead prescription drug product candidate for the treatment of various forms of watery diarrhea in dogs. Neonorm ™ Calf is the Company's lead non-prescription product. 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 ™ 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 filed nine Investigational New Animal Drug applications, or INADs, with the FDA's Center for Veterinary Medicine 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 anticipated receipt from the FDA's CVM of conditional approval for an indication for CID, and the expected commercial launch of Canalevia ™ for CID in dogs by early 2016, and the possible future expansion of labeled indications for Canalevia ™ beyond CID to include general watery diarrhea. 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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