Jaguar Animal Health Submits All Required Major Technical Sections of New Animal Drug Application for Canalevia

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Company Prepares for New Prescription Drug Launch in First Half of 2016 for Dogs Suffering from Chemotherapy-Induced Diarrhea

SAN FRANCISCO--(BUSINESS WIRE)--Aug. 19, 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 has submitted all required major technical sections of its New Animal Drug Application ("NADA") for Canalevia ™ to the U.S. Food & Drug Administration's Center for Veterinary Medicine ("CVM") for Phased Review. Canalevia is the Company's proposed Minor-Use Minor-Species ("MUMS") drug candidate for dogs suffering from chemotherapy-induced diarrhea ("CID").

Canalevia is a canine-specific formulation of crofelemer, a novel, first-in-class, anti-secretory active pharmaceutical ingredient that has been 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 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

The regulatory review process for an animal drug requires the sponsor, the entity assuming responsibility for compliance with applicable regulatory provisions as well as marketing of a new drug, to submit an NADA to the CVM for approval prior to marketing. For companion animals, there are four major technical sections to the NADA that must be filed, including 1.) Target Animal Safety, 2.) Effectiveness 3.) Chemistry, Manufacturing and Controls, and 4.) Environmental Impact. In a Phased Review submission, each technical section can be submitted independently and thus reviewed independently. The Phased Review option speeds the approval process by allowing the CVM to review each section as they are submitted by the sponsor. When all required sections are deemed complete by the CVM, the sponsor files an Administrative NADA for full or conditional approval, which the CVM's Office of New Animal Drug Evaluation has 60 days to review.

"The Phased Review was the most appropriate route for Jaguar in order to initiate the earliest review for Canalevia. While certain technical sections were being reviewed, it provided us with ample time to schedule and conduct a pre-submission conference with the CVM prior to finalizing the submission of our CMC section. We look forward to leveraging the approval of crofelemer's Active Pharmaceutical Ingredient with data regarding our plan to utilize the same manufacturers that produce the crofelemer product approved for human use. The complete submission of all major technical sections for the NADA is in line with our expectations when we met with the CVM earlier this summer," commented Lisa Conte, Jaguar's President and CEO.

Jaguar received acknowledgement from the CVM that an initial technical section the Company submitted is complete.

The Company is pursuing a MUMS approval from the CVM for Canalevia™ for CID in dogs to shorten the timeframe to commercialization. MUMS is an FDA drug designation, similar to the orphan drug designation in humans, which is typically limited to drugs that are used to treat a small number of animals each year. The MUMS designation would allow Jaguar to make Canalevia commercially available by proving the drug is safe and that there is a reasonable expectation of effectiveness prior to collecting all necessary effectiveness data.

Jaguar is preparing for the expected commercial launch of Canalevia for CID in the first half of 2016.

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 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. 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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