Jaguar Animal Health Obtains Protocol Concurrence From FDA for Canalevia Drug Product Candidate for Treatment of Acute Diarrhea in Dogs

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SAN FRANCISCO--(BUSINESS WIRE)--Apr. 13, 2016-- 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, foals, and high value horses, announced today that it has obtained protocol concurrence from the Center for Veterinary Medicine ("CVM") of the U.S. Food and Drug Administration ("FDA") to amend the protocol for the Company's ongoing clinical field study for Canalevia ™ and utilize a 125-mg tablet of a formulation manufactured according to processes and quality standards currently approved by the FDA.

Canalevia ™ is Jaguar's lead prescription drug product candidate, intended for the treatment of diarrhea in dogs. Jaguar's pivotal field study (CANA-003) is being conducted in support of the Company's filing of a new animal drug application ("NADA") for Canalevia ™ for the treatment of acute diarrhea in dogs. This prospective, blinded, randomized, placebo-controlled study was initiated in December of last year and is being conducted on an inpatient basis at animal shelters and animal rescues across the U.S. The study will enroll at least 150 dogs exhibiting watery diarrhea, and is expected to be completed in the second half of 2016.

Jaguar has submitted to the FDA all required major technical sections towards conditional approval of Canalevia ™ for dogs suffering from chemotherapy-induced diarrhea, or "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. Canalevia ™ will be the same commercial formulation for both the CID and acute diarrhea indications.

"Utilizing a 125-mg tablet simplifies the product presentation to just one tablet strength—allowing users to safely administer one or two tablets depending on dog weight, reduces product development costs for registration batches and stability studies, and leverages the Chemistry Manufacturing and Controls filing, used in both the conditional approval of Canalevia ™ and in the broader NADA acute diarrhea program," commented Philippe Brianceau, DVM, Jaguar's chief veterinary officer.

Lisa Conte, Jaguar's president and CEO, added, "Obtaining protocol concurrence by CVM is a key milestone that aligns the development of the 125-mg crofelemer tablet for both the treatment of CID and the treatment of acute diarrhea in dogs with the same dosage form for the human FDA-approved formulation of crofelemer."

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 currently 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 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 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, 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. SB-300 is Jaguar's prescription drug product candidate for the treatment of gastrointestinal ulcers in horses. Canalevia ™ and SB-300 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 SB-300 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.” These include statements regarding the anticipated conditional approval of Canalevia ™, Jaguar’s intention to develop formulations of SB-300 in horses and species-specific formulations of Neonorm ™ in additional target species, and the Company’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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