Jaguar Animal Health Announces Final Topline Results for Proof-of-Concept Study for Secretory Diarrhea in Dogs

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Statistically Significant Final Results Confirm Interim Conclusion That Crofelemer Treatment is Superior to Placebo

SAN FRANCISCO--(BUSINESS WIRE)--Oct. 18, 2016-- 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 final topline results today for the multicenter proof-of-concept study the Company conducted in 2015 to evaluate the safety and efficacy of crofelemer, the active pharmaceutical ingredient in Jaguar's Canalevia ™ prescription drug product candidate, for treatment of secretory, or watery, diarrhea in dogs.

Crofelemer is isolated and purified from *Croton lechleri*, a tree that is sustainably harvested and contains anti-secretory properties. Crofelemer has demonstrated efficacy in numerous human clinical trials 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 in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy, often a chronic problem, and was launched commercially by Napo Pharmaceuticals, Inc. last week under the tradename Mytesi ™.

The crofelemer proof-of-concept study was comprised of two stages. Stage 1 was a randomized, double-blind, placebo-controlled stage to assess the efficacy of crofelemer administered orally in alleviating clinical signs associated with secretory diarrhea in dogs, and to assess the safety of the product candidate. Stage 2 of the study was an open-label continuation of the safety assessment of crofelemer for the same indication and was not placebo-controlled. During Stage 1, 61 dogs were evaluated, and 53 dogs were evaluated during Stage 2.

During Stage 1, dogs exhibiting a fecal score of 4 (watery, liquid stool) or 5 (severe watery diarrhea) on a scale of 1 to 6 were randomized to receive either an enteric-coated crofelemer formulation, or a matching enteric-coated placebo formulation, administered twice a day for 72 hours, in addition to receiving standard of care therapy. Stool consistency and frequency were assessed at multiple time periods daily during the in-life portion of the study, which consisted of a 72-hour treatment period, followed by an observation period.

On February 19, 2015, Jaguar announced the results of an interim analysis of data from Stage 1 of the study. The interim analysis was based on 39 dogs with secretory diarrhea that took part in the study up to February 12, 2015. The statistically significant results for the 39-dog group showed crofelemer treatment to be superior to placebo in a resolution analysis of diarrhea, measured as a percentage of crofelemer-treated dogs (91.0%) that achieved formed stools (a fecal score of 1 or 2) during the evaluation period versus placebo-treated animals (50.0%), with a p-value of 0.007.

From February 12, 2015 to February 19, 2015, an additional 22 dogs with secretory diarrhea were enrolled in Stage 1 of the study. The results for the combined group of 61 Stage 1 dogs were also statistically significant, showing crofelemer treatment to be superior to placebo in the resolution of diarrhea, measured as a percentage of crofelemer-treated dogs (93.1%) that achieved formed stools (a fecal score of 1 or 2) during the evaluation period versus placebo-treated animals (68.8%), with a p-value of 0.0237.

Jaguar is in the midst of a final pivotal field study to evaluate the safety and efficacy of Canalevia ™ for treatment of acute diarrhea in dogs. An estimated 200 dogs will be enrolled in the Canalevia ™ pivotal study, which is expected to complete enrollment around the end of 2016.

"We're very pleased that the results for the additional 22 dogs enrolled in Stage 1 of the proof-of-concept study support the conclusion that crofelemer has the potential to serve as an effective new tool in the treatment of canine secretory diarrhea, and that these data are consistent with the power calculations for our ongoing field study to support approval of Canalevia ™ for acute diarrhea," stated Lisa Conte, Jaguar's president and CEO. "We estimate that U.S. veterinarians see approximately six million annual cases of acute and chronic watery 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 real problem for dog-owning families."

As the Company announced on April 13, 2016, it has obtained protocol concurrence from the Center for Veterinary Medicine ("CVM") of the U.S. Food and Drug Administration for the Canalevia ™ pivotal field study. Protocol concurrence for the pivotal study was achieved following a discussion with CVM of the clinical relevance of the results of the interim analysis Jaguar conducted on the initial 39 dogs enrolled in Stage 1 of the crofelemer proof-of-concept study.

"Following discussions with CVM regarding the clinical relevance of the proof-of-concept study and discussions about our clinical trial rigor in the ongoing field trial, which involves collecting data during the 72-hour treatment period with a 24-hour observation period, Jaguar and CVM agreed that

the pivotal study protocol for Canalevia ™ would define a responder as a dog that does not exhibit watery stool for a 16-hour window during the 72-hour study period or during the following 24-hour observation period," explained Dr. Michael Guy, a Jaguar vice president and clinical veterinarian.

Jaguar expects to file the new animal drug application ("NADA") for Canalevia ™ in 2017 for the indication of acute diarrhea in dogs and to conduct the commercial launch of the product, if it is approved. Jaguar has also established an investigational new animal drug (INAD) file for Canalevia ™ for chemotherapy-induced diarrhea ("CID") in dogs, for which it has received MUMS designation.

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 acute diarrhea in dogs. According to the American Veterinary Medical Association, there were approximately 70 million dogs in the United States in 2012.

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 Mytesi ™

Mytesi ™ (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi ™ is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi ™. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

More information and complete Prescribing Information are available at Mytesi.com.

About Napo Pharmaceuticals, Inc.

San Francisco-based Napo Pharmaceuticals, Inc., focuses on the development and commercialization of proprietary pharmaceuticals from rainforest resources for the global marketplace in collaboration with local partners. Recently, Napo and Jaguar Animal Health, Inc. (NASDAQ: JAGX), 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 plans for a proposed merger of the two companies.

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 the expected completion of enrollment around the end of 2016 for Jaguar's pivotal study for Canalevia ™, the estimate that 200 dogs will be enrolled in the Canalevia ™ pivotal study, the Company's plans to file the new animal drug application ("NADA") for Canalevia ™ for the indication of acute diarrhea in dogs in 2017, Jaguar's plan to conduct the commercial launch of Canalevia ™ for the indication of acute diarrhea in dogs, if the product is approved, 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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