



## Jaguar Animal Health Announces Outcome of Canine Proof-of-Concept Study for Canalevia

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*Statistically Significant Results Support the Conclusion that Canalevia Treatment is Superior to Placebo*

*91.0% of Treated Dogs Achieved a Formed Stool During the Study Versus 50.0% of Placebo-treated Animals*

**San Francisco, CA (February 19, 2015):** Jaguar Animal Health, Inc. (“Jaguar”), an animal health company focused on developing and commercializing first-in-class gastrointestinal and other proprietary health products for companion and production animals, announced today significant top-line results of its recently completed, controlled, proof-of-concept study to evaluate the clinical benefits of Canalevia™, 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, a novel, first-in-class, anti-secretory active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. 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.

The Canalevia study was a multicenter, randomized, double-blind, controlled study to assess the efficacy of Canalevia administered orally in alleviating clinical signs associated with secretory, or watery, diarrhea in dogs. Dogs experiencing unformed or watery stools without blood were randomized to receive either Canalevia (a proprietary enteric-coated crofelemer formulation), or a matching enteric-coated placebo formulation, administered twice a day for three days, in addition to receiving standard of care therapy. Stool consistency and frequency were assessed at multiple time periods daily for the three treatment days. A total of 39 dogs with secretory diarrhea, randomized across multiple centers, 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 this study were based on experience and success in previous human and dairy calf studies evaluating *Croton lechleri*-derived products and their effect on watery diarrhea,” stated Lisa Conte, Jaguar’s CEO. “These encouraging results underscore our confidence that Canalevia will be a new tool in the treatment of canine watery diarrhea—and the coincident health and quality of life issues for both dogs and their owners—and that other first-in-class, *Croton lechleri*-derived products will promote health and the management of diarrhea in the multiple additional animal species targeted by Jaguar.”

The results of this study will be used to design a pivotal trial, targeted for conclusion in 2015, in support of the filing of a new animal drug application (“NADA”) for Canalevia for the indication of general watery diarrhea in dogs. Jaguar currently has an Investigational New Animal Drug (INAD) application on file for Canalevia for chemotherapy induced diarrhea (“CID”) in dogs. Canalevia will be the same commercial formulation for both the CID and general watery 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. “We estimate that in the 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 families with dogs,” Conte explained.

### **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, beef-flavored chewable formulation of crofelemer that we are developing for the treatment of chemotherapy-induced diarrhea, or CID, in dogs. The product is not absorbed systemically but acts locally in the gastrointestinal tract. It acts at the last physiological step, conserved across mammalian species, in the manifestation of watery diarrhea, regardless of cause.

### **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](http://www.jaguaranimalhealth.com).

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