



Jaguar Animal Health Files Ninth Investigational New Animal Drug Application

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Drug Candidate Addresses Gastric, Intestinal and Colonic Ulcers in Horses and Foals

San Francisco, CA (February 10, 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 that it has submitted an Investigational New Animal Drug application (“INAD”) with the Center for Veterinary Medicine (“CVM”) of the U.S. Food and Drug Administration for the treatment and prevention of recurrence of ulcers, and the treatment of diarrhea, in horses and foals. This is the ninth INAD Jaguar has filed.

This new animal drug is being investigated for the treatment and prevention of the recurrence of ulcers throughout the gastrointestinal tract, including gastric, intestinal, and colonic ulcers occurring in the stomach, intestine, and colon, as well as the treatment of diarrhea often present in horses suffering from ulcers. The proprietary oral formulation of the drug will contain a number of active ingredients, including an anti-secretory agent for watery diarrhea derived from the *Croton lechleri* tree. To begin development of a drug for animal use, a company must first file an INAD with the CVM and schedule discussions with the CVM to determine the types of studies that will be used to support safety, effectiveness and manufacturing.

According to a study published in the *Journal of Equine Veterinary Science* in March 2005, 54% of performance horses have both colonic and gastric ulcers and 97% of performance horses have either a gastric or a colonic ulcer. “We estimate that there are more than 3.9 million performance horses in the United States,” commented Lisa Conte, Jaguar’s CEO. Michael Hauser, DVM, MS, Jaguar’s Chief Veterinarian of Clinical Operations, added, “Although there are products available to treat and prevent gastric ulcers, Jaguar’s new drug candidate will also treat and prevent intestinal and colonic ulcers. Ulcers are lesions that may be manifested clinically, with protein and blood loss, enteritis and colitis. Subclinically, the lesions cause general unthriftiness, intermittent loose stools, possible vague signs of low-grade colic, and compromised athletic performance.”

According to Tim Dotson, Jaguar’s Executive Director of Regulatory Affairs, “There are currently no FDA-approved new animal drugs available for the treatment of colonic ulcers in horses, thus making this product a complete, first-in-class ulcer and gut treatment for more active horses like performance and racing horses as well as for horses used recreationally.”

In February of 2014 Jaguar filed an INAD for a formulation of crofelemer intended to treat acute colitis in horses. A human specific formulation of crofelemer, Fulyzaq, was approved by the U.S. FDA in 2012 for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

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.

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