



Jaguar Animal Health Initiates Filing of Its First New Animal Drug Application with FDA

December 22, 2014

Canalevia™ is a New Prescription Drug Candidate for Treatment of Dogs Undergoing Chemotherapy

San Francisco, CA (December 22, 2014): Jaguar Animal Health, Inc., an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, announced today that it has initiated the filing of the Company's first New Animal Drug Application (NADA) with the U.S. Food and Drug Administration. The filing was submitted for Jaguar's Canalevia prescription drug candidate, a proposed minor-use minor-species (MUMS) drug for use in dogs undergoing chemotherapy.

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. Receipt of MUMS designation would allow Jaguar to make Canalevia commercially available before collecting all necessary effectiveness data, but after proving the drug is safe and showing that there is a reasonable expectation of effectiveness.

"Following the pre-development conference between Jaguar and FDA representatives which took place on October 22nd of 2014, we are initially pursuing conditional FDA approval for Canalevia for dogs undergoing chemotherapy pursuant to MUMS designation—an approach we expect will allow us to bring this new tool for management of certain chemotherapy side effects to dogs in need as soon as possible."

Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the Croton lechleri tree. 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. Canalevia is a first-in-class anti-secretory agent under development in multiple animal species for watery diarrhea of any 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. Neonorm™ Calf is the company's lead non-prescription product. Neonorm is a standardized botanical extract derived from the Croton lechleri tree. Canalevia is Jaguar's lead prescription drug product candidate proposed for use in dogs undergoing chemotherapy. Canalevia is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified 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 eight investigational new animal drug applications, or INADs, with the FDA and intends to develop species-specific formulations of Neonorm in six additional target species.

For more information, please visit www.jaguaranimalhealth.com.

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