

Jaguar Animal Health, Inc. Files Eighth Investigational New Animal Drug Application

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SAN FRANCISCO--([BUSINESS WIRE](#))--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 its eighth Investigational New Animal Drug application (“INAD”) with the Center for Veterinary Medicine (“CVM”) of the U.S. Food and Drug Administration for the treatment of insulin-resistance and metabolic syndrome in dogs. 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.

“Insulin resistance and metabolic syndrome occurs not just in humans, but also in dogs. However, while physicians worldwide have a vast array of drugs that have been approved to treat this condition in humans, veterinarians have no approved products available to treat these issues in dogs.”

The most recent drug candidate in Jaguar’s pipeline is being developed for the treatment of obesity-related metabolic dysfunction in dogs, which manifests in altered lipid profiles, insulin resistance and mild hypertension. These metabolic disturbances affect the health of the dogs and could decrease their lifespan. According to a 2012 national survey of veterinarians, approximately 21% of dogs in the U.S. are obese. Obesity is more common in elderly dogs, as well as in neutered dogs.

Jaguar’s Chief Veterinary Officer, Serge Martinod, DVM, Ph.D., commented, “Insulin resistance and metabolic syndrome occurs not just in humans, but also in dogs. However, while physicians worldwide have a vast array of drugs that have been approved to treat this condition in humans, veterinarians have no approved products available to treat these issues in dogs.”

The new prescription drug candidate is isolated and purified from a plant indigenous to the southwestern United States. In traditional medicine, the plant was brewed as a tea and used for the treatment of diabetes and other various illnesses. The prescription drug candidate has been previously evaluated in Phase 2 studies in humans, and is also the subject of INADs previously filed by Jaguar for the treatment of Type II diabetes in cats and metabolic syndrome in horses.

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 the Company’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 to address the symptoms of watery diarrhea, or scours, in preweaned dairy calves, for which a commercial launch is planned in the United States by the end of 2014. Canalevia™ is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. Neonorm is a 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 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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