



## Jaguar Animal Health Announces Positive Topline Results of University Study of Second-Generation Formulation of Neonorm Calf and Commercialization Strategy Updates

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*Advances commercialization strategy for equine and companion animal drug product candidates*

SAN FRANCISCO--(BUSINESS WIRE)--Jun. 17, 2016-- Jaguar Animal Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company"), 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 positive topline results today from its study conducted in conjunction with researchers from Cornell University College of Veterinary Medicine ("Cornell") to evaluate the efficacy of the prophylactic use of a second-generation, powder formulation of Neonorm™ Calf, administered in liquid, on naturally occurring diarrhea in preweaned dairy calves and to investigate the possible prebiotic benefit of the product.

Neonorm™ Calf, one of the Company's lead non-prescription products, has been formulated and clinically tested to help proactively retain fluid in dairy calves and reduce the severity of diarrhea—aiding the animals in avoiding debilitating, dangerous levels of dehydration associated with scours. The powder form of the product allows for ease of administration for entire herd management.

The double-blind, randomized study conducted in association with Cornell involved 40 Holstein bull calves that were affected with naturally occurring diarrhea. The study compared prophylactic use of Neonorm™ Calf against a placebo, administered twice daily. Data regarding fecal dry matter ("FDM") was used to measure water loss due to secretory diarrhea. Body weight measurements were performed daily to determine average daily weight gain during the 25-day study. Blood and fecal samples were also collected, along with data related to bacterial genus prevalence in the intestinal microbiome.

"Based on the FDM findings, which are an objective measurement of hydration and improvement in diarrheal disease, the topline results of the study show a significant effect in decreasing the severity of the disease, along with an improvement in the hydrating of the patients. Over the next several weeks, a detailed analysis will be conducted on specific endpoints. Additionally, characterization of the fecal microbiome throughout the study period will allow us to determine if, under natural conditions, the product may positively alter the intestinal microbiome to the benefit of the host—possibly resulting in improved efficiency of feed conversion and increased weight gain," commented Dr. Rodrigo Bicalho, Associate Professor of Dairy Production Medicine at Cornell Veterinary School, and the principal investigator of the study.

The microbiome is a community of microorganisms that live normally in the gut and are vital to maintenance of gut health. In October of last year Jaguar announced that a study by Cornell researchers supports a benefit of Neonorm™ Calf on the optimization of the intestinal microbiome profile in preweaned dairy calves.

### **Commercialization Strategy Updates for Jaguar's Equine and Companion Animal Drug Product Candidates**

The reception among users of Neonorm™ Foal, the anti-diarrheal for newborn horses that Jaguar launched early this year with a nationwide campaign offering samples, has been overwhelmingly positive. User feedback regarding Neonorm™ Calf also continues to be very favorable. Commercialization of these two non-prescription products has provided numerous benefits that the Company intends to leverage during the expected introductions of high value, first-in-class prescription drug products into the U.S. marketplace and beyond. The commercialization process has allowed Jaguar to extend to animals the clinical utility of the novel mechanism of action of *Croton lechleri*-derived anti-secretory products, refine messaging to veterinarians, fine-tune internal processes, forge commercial manufacturing relationships, and develop commercial infrastructure with important distributors relevant to both prescription and non-prescription products.

"The clinically-proven performance of Neonorm™ Foal, in combination with our heightened understanding of the vast and unmet need for novel and differentiated ulcer treatment within the equine athlete space, is driving our increased focus on equine product and market development. As part of our equine franchise, we will continue commercial efforts around Neonorm™ Foal, and focus on preparations for the expected commercial launch of SB-300, our drug product candidate for equine gastric ulcer syndrome. We believe SB-300 will be an important product introduction, with performance attributes differentiated from proton pump inhibitors such as omeprazole. We are also focusing resources on the expected commercial launch of Canalevia™, our drug product candidate for acute diarrhea in dogs," stated Lisa Conte, Jaguar's president and CEO.

"In addition to being the Jaguar drug product candidates that are furthest in development, Canalevia™ and SB-300 offer the largest market opportunities, in our opinion. As a result, considering the difficult capital markets, we are focusing our resources on these nearer-term expected value drivers, and are therefore shifting our planned development activities for several other products into late-2016 and 2017," Conte said.

In order to focus the Company's resources on its nearer-term expected value drivers, Jaguar is shifting the planned development activities for drug

product candidates to treat acute diarrhea in cats and for feline herpes virus from 2016 to 2017.

The Company will also delay commercial planning activities for the conditional approval of Canalevia™ for the indication of chemotherapy-induced diarrhea ("CID") in favor of concentrating more heavily on the expected commercial launch, in 2017, of Canalevia™ for acute diarrhea in dogs. Although Jaguar has received MUMS designation for Canalevia™ for the treatment of CID in dogs, the Company believes there is a much larger market opportunity for the treatment of acute diarrhea in dogs. The Company's pivotal field trial of Canalevia™ for acute diarrhea in dogs is currently underway. Additionally, Jaguar intends to address the important unmet medical need of chemotherapy-induced diarrhea with a pilot program to investigate the best programs for management of diarrhea in dogs with certain novel cancer agents, such as tyrosine kinase inhibitors, commonly used in long-term canine and human cancer management.

Canalevia™ and SB-300 are under license for exclusive global rights to Jaguar from Napo Pharmaceuticals, Inc. ("Napo"). Napo and Jaguar have been engaged in exploratory discussions since February 2016 regarding a potential merger and/or other ways to cooperate with their respective business endeavors. A human formulation of crofelemer was approved by the FDA in 2012 for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

Neonorm™ Calf remains an important asset for the Company and is the focus of future business development activities. Jaguar is also focused on business development discussions for other indications of its products, in particular in the international arena.

#### **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. SB-300 is Jaguar's prescription drug product candidate for the treatment of gastrointestinal ulcers in horses. Canalevia™ and SB-300 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 SB-300 in horses, and Canalevia™ for cats and dogs.

For more information, please visit [www.jaguaranimalhealth.com](http://www.jaguaranimalhealth.com).

#### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the possibility that the second-generation, powder formulation of Neonorm™ Calf may positively alter the intestinal microbiome to the benefit of the host, the possible beneficial effects of this product on the efficiency of feed conversion and on weight gain, the expected commercial launch of SB-300, the Company's belief that SB-300 will be an important product introduction, with performance attributes differentiated from proton pump inhibitors such as omeprazole, the expected commercial launch of Canalevia™ for acute diarrhea in dogs, Jaguar's assumption that Canalevia™ and SB-300 offer the largest market opportunities, the Company's plans to address the unmet medical need of CID with a pilot program to investigate the best programs for management of diarrhea in dogs, future business development activities, Jaguar's intention to develop formulations of SB-300 in horses and species-specific formulations of Neonorm™ in additional target species, and the Company'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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