Jaguar Animal Health Initiates Proof-of-Concept Study to Evaluate Safety, Tolerability & Efficacy of Neonorm in Foals

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SAN FRANCISCO--(BUSINESS WIRE)--Sep. 25, 2015-- 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, announced today that it has launched a proof-of-concept study to determine the safety, tolerability, and efficacy of Neonorm ™ Foal Plus, an equine formulation of Jaguar’s actively marketed Neonorm ™ Calf product in combination with an added probiotic, for use in foals with secretory or watery diarrhea.

Neonorm ™ Foal Plus consists of a standardized botanical extract (Neonorm ™) in combination with a third-party probiotic. Probiotics are live organisms that are widely used in the treatment of diarrhea in humans[1], small animals[2] and equines. Benefits of their use have been demonstrated in third-party human trials, and a third-party trial of probiotics in foals demonstrated increased weight gain in the treated animals[3].

The objective of Jaguar’s randomized, multi-site, blind-controlled foal study is to determine the safety, tolerability, and efficacy of Neonorm ™ Foal Plus when administered orally in a paste formulation. Approximately 60 foals will be enrolled in the six-day study, each randomly assigned to one of three different treatment groups. Fecal scoring will be conducted every six hours during the treatment period, and twice daily during the observation period. Exploratory outcome evaluations will also include the use of abdominal ultrasound before and after treatment, and between treatment groups. The initiation of the study is taking place in Argentina, where it is currently foaling season.

“Although probiotics are commonly used in foals, there are currently no anti-secretory products commercially available for the foal market. We believe the combination of probiotics with the novel, anti-secretory mechanism of action of Neonorm ™ will produce a new and highly efficacious standard of care for the management of gut health, stool formation and the normalization of hydration in foals,” explained Lisa Conte, Jaguar’s president and CEO. “We are excited about this study, and look forward to the expected commercial launch of Neonorm ™ Foal Plus, targeted for this December during the American Association of Equine Practitioners Trade Show in Las Vegas.”

Published studies estimate that there were 9.2 million horses in the U.S. in 2005. Data from the Food and Agriculture Organization of the United Nations indicate that there were approximately 5.7 million horses in Europe in 2013 and nearly 60 million horses in 2013 worldwide. Diarrhea is among the most common clinical complaints in foals and often takes place in the first 30 days of a foal's life. The debilitating and devastating ramifications of dehydration that often occur as a result of secretory diarrhea in foals can manifest quickly, have long-term health implications, and result in death.

Neonorm ™ Calf, the Company’s lead non-prescription product, contains the same standardized botanical extract as Neonorm ™ Foal Plus and has been clinically demonstrated to address the normalization of stool formation and ion and water flow in the intestinal lumen of preweaned dairy calves. The Neonorm ™ standardized botanical extract is derived from the *Croton lechleri* tree, which is sustainably harvested. Jaguar currently owns enough of this extract to formulate a combination of approximately one million treatments of Neonorm ™ Calf or Neonorm ™ Foal Plus.

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.

Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements.” These include statements regarding the Company’s belief that the combination of probiotics with Neonorm ™ will produce a new and highly efficacious standard of care for the management of gut health, stool formation and the normalization of hydration in foals, and the expected commercial launch of Neonorm ™ Foal Plus this December. 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.

[1] Food and Agricultural Organization of the United States and World Health Organization (Online), 2001.

[2] Marks, SL. *Probiotics, prebiotics and synbiotics. What are they and when should they be implemented?* Proceedings of the 34th World Small animal Veterinary congress 2009. IVIS

[3] Schoster A, Weese JS, Guardabassi L. *Probiotic use in horses – What is the evidence for their clinical efficacy*? J Vet Int Med Vol 28 (6) 1640-1652, 2014.

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