



Jaguar Animal Health Initiates Proof-of-Concept Study to Evaluate the Safety and Effectiveness of an Investigational New Animal Drug Candidate for the Treatment of Gastrointestinal Ulcers in Horses

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SAN FRANCISCO--(BUSINESS WIRE)--Nov. 5, 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 evaluate the safety and effectiveness of its investigational new animal drug currently referred to as SB-300. SB-300 is a pharmaceutical formulation of a standardized botanical extract from the *Croton lechleri* tree, which is sustainably harvested, for the treatment of gastrointestinal ulcers in horses.

Stall confinement, stress, intermittent feeding, intense exercise and administration of non-steroidal anti-inflammatories are factors that may lead to gastric ulcers in horses¹ and, frequently, in performance equine athletes. Horses with gastric ulcers may perform poorly, which makes this condition a sizable economic as well as health problem within the horse industry².

The Amazonian herbal medicine Sangre de Grado, which, like SB-300, is derived from the *Croton lechleri* tree, has been used in traditional medicine in humans for thousands of years for ulcers and gastric distress and has been shown to be an effective anti-ulcerogenic agent in rats^{3, 4}. SB-300 acts locally in the gastrointestinal tract with minimal systemic absorption, a key factor for the safety of the product. Additionally, SB-300 has no effect on gut motility and there have been no significant drug-drug interactions identified to date.

Jaguar's prospective, masked, randomized, negative controlled study will enroll horses with gastric ulcers. Participating animals will be dosed for 28 consecutive days and will undergo gastroscopy every 14 days, during which gastric ulcer scores and gastric pH will be recorded. Study results are expected to be available by the end of the year.

According to a third-party 2005 study, 54% of performance horses have both colonic and gastric ulcers and 97% of performance horses have either a gastric (87%) or a colonic (63%) ulcer.⁵ Data from the American Horse Council states that there are currently 9.2 million horses in the U.S., a population that includes 844,531 race horses, more than 2.7 million show horses, and more than 3.9 million recreational horses. 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.

Jaguar announced this past September that it recently initiated a proof-of-concept study in Argentina to evaluate the safety, tolerability and efficacy of Neonorm™ Foal, an equine extension of Jaguar's lead non-drug product, Neonorm™ Calf. This study has completed enrollment and results are expected in the next few weeks. Jaguar is planning for the launch of Neonorm™ Foal at the American Association of Equine Practitioners Annual Convention, which takes place December 5–9 in Las Vegas.

Additionally, Jaguar is planning trials to develop an equine-specific formulation of crofelemer for the treatment of diarrhea associated with acute colitis, a devastating and dehydrating condition that can lead to patient death in less than 24 hours. Crofelemer is an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. The Company intends to seek MUMS (minor use in a major species) designation for the product.

"Jaguar is developing a full suite of products to support and improve gastrointestinal health in foals and adult horses," stated Lisa Conte, Jaguar's president and CEO. "Gastrointestinal conditions such as watery diarrhea, ulcers and acute colitis can be extremely debilitating for horses, and present a significant economic and emotional burden for veterinarians and owners around the world."

The Neonorm™ extract is also the core ingredient in Neonorm™ Calf, the Company's lead non-drug product, and in Neonorm™ Foal. Jaguar currently owns enough of this extract to formulate a combination of approximately one million doses of Neonorm™ Calf or Neonorm™ Foal.

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 diarrhea in dogs. Neonorm™ Calf is the Company's lead non-drug 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 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, 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 availability, before year-end, of results from Jaguar’s proof-of-concept study to evaluate the safety and effectiveness of SB-300 for the treatment of gastrointestinal ulcers in horses, the availability, in the next few weeks, of results from Jaguar’s proof-of-concept study in Argentina to evaluate the safety, tolerability and efficacy of Neonorm™ Foal, Jaguar’s plan to launch Neonorm™ Foal at the American Association of Equine Practitioners Annual Convention this December, the Company’s intention to develop, and seek MUMS designation for, an equine-specific formulation of crofelemer for the treatment of acute colitis, Jaguar’s intention to develop species-specific formulations of Neonorm™ in six additional target species, and the Company’s plan to develop formulations of Canalevia™ for cats, horses 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.

¹Habershon-Butcher, J.L., Hallowell, G.D., Bowen, I.M., Sykes, B., 2012. *Prevalence and risk factors for ulceration of the gastric glandular mucosa in thoroughbred race horses in training in the U.K and Australia*. J. Vet. Intern. Med. 26, 731.

²Vatistas, N.J., Synder, J.R., Carlson, G., Johnson, B., Arthur, R.M., Thurmond, M., Zhou, H. and Lloyd, K.L.K. (1999) *Cross-sectional study of gastric ulcers of the squamous mucosa in thoroughbred racehorses*. Equine Vet. J. 31.

³Cordeiro KW, Pinto LA, Nazari Formagio AS et al. *Antiulcerogenic effect of Croton Urucurana Baillon bark*. Journal of ethnopharmacology 143 (2012) 331-337.

⁴Miller MJ, MacNaughton WK, Zhang XJ et al. *Treatment of gastric ulcers and diarrhea with the Amazonian herbal medicine sangre de grado*. Am J Physiol Gastrointest Liver physiol 279 (2000) 192-200.

⁵Pellegrini FL (2005). *Results of a large-scale necroscopic study of equine colonic ulcers*. J Equine Vet Sci; 25 (3): pp. 113-117.

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