



## **Jaguar Animal Health Reports Topline Findings for its 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**

January 28, 2016

SAN FRANCISCO--(BUSINESS WIRE)--Jan. 28, 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, and high-value horses, announced positive topline results today from its 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.

In this prospective, blinded, randomized, negative controlled study, Standardbred or Thoroughbred racehorses were randomized to one of three groups (10 horses per group) and treated for 28 days: horses in the placebo group received water-filled syringes every 6 hours; those in the TRT5 group received 5 grams of SB-300 divided into 2 doses per day; and those in the TRT40 group received 40 grams of SB-300 divided into 4 doses per day. Strict enrollment criteria required patients to have both squamous (non-glandular) and glandular gastric ulcerations. All horses were examined by gastroscopy (stomach endoscope) by blinded equine investigators on Day 0 (prior to treatment; baseline), and on Day 14 (mid-study), Day 28 (last day of treatment) and Day 35 (7 days after last treatment). Treatment-related adverse events were not observed.

With respect to glandular ulcerations, a statistically significantly greater number of horses in both the TRT40 (89%) and the TRT5 (78%) group had an improvement or a resolution of glandular ulcerations, compared with the placebo (25%) group as soon as Day 14. By Day 35, all of the SB-300 treated horses had experienced improvement or resolution, whereas 25% of horses in the placebo group still had not improved or resolved during the study.

With respect to squamous ulcerations, a non-statistically significant dose-dependent effect was observed with 40% and 33% of horses achieving an improvement or a resolution by Day 14 in the TRT40 and TRT5 groups, respectively, compared with 11% of placebo horses. By Day 35, numerically more horses in the TRT40 (60%) and TRT5 (55%) groups had achieved an improvement or a resolution compared with 33% of placebo horses.

Jaguar will be releasing additional findings from this study after further analysis of the data.

As Jaguar stated on November 5<sup>th</sup> of last year in a press release announcing the initiation of this study, stall confinement, stress, intermittent feeding, intense exercise and administration of non-steroidal anti-inflammatories are factors that may lead to gastric ulcers in horses<sup>1</sup> and, frequently, in performance equine athletes. Horses with gastric ulcers may perform poorly, which makes this condition an economic as well as health problem within the horse industry<sup>2</sup>.

According to a third-party 2005 study, as many as 55% of performance horses have both colonic and gastric ulcers, and 97% of performance horses have either a gastric (87%) or a colonic (63%) ulcer.<sup>3</sup> 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.

### **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. 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™ 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, and formulations of Canalevia™ for cats, horses 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 Jaguar's plans to develop an

FDA-approved, first-in-class complete ulcer and gut treatment for horses, the Company's plan to release additional findings from its recently completed proof-of-concept study, Jaguar's intention to develop species-specific formulations of Neonorm™ in 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.

<sup>1</sup>Habershon-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.

<sup>2</sup>Vatistas, 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.

<sup>3</sup>Pellegrini 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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Source: Jaguar Animal Health, Inc.

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