



## **Jaguar Animal Health Initiates Dose Determination Study with the Target Commercial Paste Formulation of SB-300, the Company's Drug Product Candidate for Treatment of Equine Gastric Ulcer Syndrome**

May 4, 2016

SAN FRANCISCO--(BUSINESS WIRE)--May 4, 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 today that it has initiated a dose determination study of the target commercial paste formulation of SB-300, the Company's drug product candidate for the treatment of Equine Gastric Ulcer Syndrome ("EGUS"). The primary objective of the study is to select the commercial dose of SB-300 for the treatment of EGUS.

SB-300 is a pharmaceutical formulation of a standardized botanical extract. The randomized, blinded, controlled, multisite dose determination study will last 30 days and enroll approximately 100 race horses that are two years of age or older. All enrolled horses will be diagnosed with glandular and squamous gastric ulcers, via gastroscopy on Day 0 prior to treatment and evaluated after 14 and 28 days during treatment. Enrolled horses will be randomized to one of four groups each containing approximately 25 animals. The IVPa group will receive 5 grams of SB-300 every 12 hours; those in the IVPb group will receive 2.5 grams of SB-300 every 12 hours; and those in the PLBO group will receive a placebo every 12 hours. Horses in the POS group will receive the FDA-approved recommended dosage of omeprazole once a day. The percentage of horses in each group with a reduction in the number and severity (improvement or complete resolution) of gastric ulcerations will be compared to determine the proposed dosage for SB-300.

As Jaguar announced this past January, topline results from its proof-of-concept study to evaluate the safety and effectiveness of SB-300 indicate that 78 to 89% of horses treated with SB-300 (depending on dose) had resolution or improvement of glandular ulcers as soon as 14 days during treatment. As Jaguar announced this past February, further analysis of the results of the proof-of-concept study indicates that SB-300 did not alter gastric pH during the 28-day trial, or for 7 days after therapy. A treatments for EGUS that does not alter gastric pH is important because maintaining low gastric pH is essential for digestion, for gut immunity and first line defense against pathogens, for the absorption of vitamins and minerals, and for potentially additional downstream effects. As Jaguar announced earlier this month, standard drug testing in race horses that received SB-300 did not detect any substances commonly disallowed by horse racing authorities.

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. 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>1</sup>

The positive reception among users of Neonorm Foal, the anti-diarrheal product Jaguar launched for newborn horses early this year, in combination with the Company's heightened understanding of market needs within the global equine space, is driving Jaguar's increased focus on equine product development.

### **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, visit [www.jaguaranimalhealth.com](http://www.jaguaranimalhealth.com) or connect with us on [Facebook](#).

### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding 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.

<sup>1</sup>Pellegrini FL. Results of a large-scale necroscopic study of equine colonic ulcers. *J Equine Vet Sci.* 2005;25(3):113-117.

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