Jaguar's SB-300 Drug Product Candidate in Development

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Advantages as an Alternative Approach to the Management of Gastrointestinal Ulcers in Horses

SAN FRANCISCO--(BUSINESS WIRE)--Feb. 16, 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 horses, released additional findings today from its recently completed 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 Equine Gastric Ulcer Syndrome (EGUS).

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.

The press release Jaguar issued on January 28, 2016 announced positive topline results from the study. Further analysis of the study results indicates that SB-300 did not alter gastric pH during the 28-day trial, or for 7 days after therapy. Gastric pH during therapy was observed to be similar to baseline gastric pH at all measured study time points. "Whereas other ulcer treatments (e.g. proton pump inhibitors like omeprazole) rely on a mechanism of action that blocks gastric acid secretion for the treatment and prevention of EGUS, our preliminary data indicate that SB-300 may have advantages," stated Lisa Conte, Jaguar's president and CEO. "Treatments for EGUS that do not alter gastric pH are 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 other downstream effects."

As Jaguar announced on January 28th, 2016, the results of the Company's study 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. Published studies[1,2] with omeprazole have demonstrated that between 14 and 34% of horses diagnosed with EGUS are observed with resolution or improvement of glandular ulcers when used at the manufacturer's recommended treatment duration of 28 days.

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.[3] Stall confinement, stress, intermittent feeding, an overreliance on grain in place of grazing, intense exercise, and administration of non-steroidal anti-inflammatories are factors that may lead to gastric ulcers in horses.[4] "Ulcers are lesions that may be manifested both clinically and subclinically, significantly compromising both health and athletic performance in horses," stated equine veterinarian members of Jaguar's clinical operations team.

SB-300 may offer horse owners an additional advantage over omeprazole in the competition horse world, where the requirement exists for equine athletes to compete free from the effect of any drugs. International screening limits for horse racing state that omeprazole has a 72-hour detection time. Detection time is defined as the first observed time point at which urine and/or plasma samples collected from a horse are negative for the presence of a specified drug. "Because SB-300 acts locally in the gut and is minimally absorbed, it is unlikely that use of this drug product candidate will present any issues related to detection time," explained Conte. "We intend to demonstrate that SB-300 is not systemically absorbed in horses, thereby providing a treatment regimen that can continue without mandatory withdrawal prior to competition. Moreover, we also aim to demonstrate that SB-300 can be administered in the presence of feed, another constraint of omeprazole administration."

Following the late stage development toward anticipated FDA approval of SB-300, Jaguar plans to focus initial promotional efforts on the segment of the equine market that is most likely to seek treatment for EGUS: owners and caregivers of high-value horses, equine athletes, and horses that are insured. According to the American Veterinary Medical Association, an estimated 9% of horse owners in the U.S. have insurance for the animals. "It is clear that development of a natural alternative treatment for EGUS that maintains stomach health without altering stomach pH is desirable," Conte said. "We plan to initiate further studies to differentiate the benefits that we believe SB-300 will offer to equine athletes challenged with glandular ulcers, and our goal is to see SB-300 serve as an important tool in the standard of care."

The U.S. patent for use of omeprazole to treat equine ulcers expired in 2015.

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, 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.

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 belief that SB-300 may offer horse owners an additional advantage over omeprazole in the competition horse world, Jaguar's intention to demonstrate that SB-300 is not systemically absorbed in horses and can be administered in the presence of feed, Jaguar's plans to focus initial promotional efforts on the segment of the equine market that is most likely to seek treatment for EGUS, the Company's plan to initiate further studies to differentiate the benefits it believes SB-300 will offer, Jaguar's goal to see SB-300 serve as the new standard of care, 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.

[1]Sykes BW, Sykes KM, Hallowell GD. A comparison of three doses of omeprazole in the treatment of equine gastric ulcer syndrome: A blinded, randomised, dose-response clinical trial. *Equine Vet J*. 2015;47(3):285-290.

[2]Sykes BW, Sykes KM, Hallowell GD. A comparison of two doses of omeprazole in the treatment of equine gastric ulcer syndrome: a blinded, randomised, clinical trial. *Equine Vet J*. 2014;46(4):416-421.

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

[4]Habershon-Butcher JL, Hallowell GD, Bowen IM, Sykes BW. Prevalence and risk factors for ulceration of the gastric glandular mucosa in thoroughbred race horses in training in the UK and Australia. J Vet Intern Med. 2012;26:731.

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Source: Jaguar Animal Health, Inc.

KCSA Strategic Communications
Garth Russell, 212-896-1250
grussell@kcsa.com
or
Allison Soss, 212-896-1267
asoss@kcsa.com