Jaguar Animal Health and Napo Pharmaceuticals Announce Filing of Two Orphan Drug Designation Applications with FDA for Mytesi for Serious Unmet Medical Needs

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Napo Applications Request Orphan Drug Designation for Mytesi for Congenital Diarrheal Disorders and Diarrhea Associated with Short Bowel Syndrome

Pursuit of Orphan Drug Designations Parallels Jaguar's Focus on MUMS (Minor Use and Minor Species) Indications for Canalevia in Dogs

SAN FRANCISCO--(BUSINESS WIRE)--Jun. 5, 2017-- Jaguar Animal Health, Inc. (NASDAQ: JAGX) (Jaguar), an animal health company focused on developing and commercializing first-in-class gastrointestinal products for companion and production animals, foals, and high value horses, and Napo Pharmaceuticals, Inc. (Napo), a human health company developing and commercializing novel gastrointestinal prescription products from plants used traditionally in rainforest areas, today announced Napo's filing of orphan drug designation applications with the U.S. Food & Drug Administration (FDA) for Mytesi® for two areas of serious unmet medical needs: Congenital diarrheal disorders and diarrhea associated with short bowel syndrome.

Napo's Mytesi ® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. The Orphan Drug Act (ODA) provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status"). Orphan designation qualifies the sponsor of the drug for various development incentives, including tax credits for qualified clinical testing and relief of filing fees.

Congenital diarrheal disorders (CDD) are a group of rare, chronic intestinal channel diseases, occurring exclusively in early infancy, that are characterized by severe, lifelong diarrhea and a lifelong need for nutritional intake either parenterally or with a feeding tube. CDDs are related to specific genetic defects inherited as autosomal recessive traits, and the incidence of CDDs is much more prevalent in regions where consanguineous marriage is part of the culture. CDDs are directly associated with serious secondary conditions including dehydration, metabolic acidosis, and failure to thrive, prompting the need for immediate therapy to prevent death and limit lifelong disability.

Short bowel syndrome (SBS) is a complex condition characterized by malabsorption of fluids and nutrients due to congenital deficiencies or surgical resection of small bowel segments. Consequently, patients suffer from symptoms such as debilitating diarrhea, malnutrition, dehydration and imbalances of fluids and salts. This could be due to either a genetic disorder or premature birth. In countries such as the United Arab Emirates and Saudi Arabia, both CDD and SBS occur with much higher incidence. Napo recently visited with medical centers in this region.

"With the early and extreme morbidity and mortality suffered by CDD and SBS patients, we welcome the opportunity to participate in the investigation of a novel drug to address the devastating diarrhea and dehydration caused by these lifelong diseases for which there is currently no available treatment except parenteral nutrition, and help limit the suffering of patients and their family members," stated Dr. Mohamad Miqdady, Chief of Pediatric Gastroenterology, Hepatology & Nutrition at Sheikh Khalifa Medical City in Abu Dhabi.

"Our focus for the orphan drug designation applications is to provide symptomatic relief for the secretory diarrhea, which begins shortly after birth and continues as a lifelong condition," commented Dr. Pravin Chaturvedi, Chair of Napo's Scientific Advisory Board. "Crofelemer, the active pharmaceutical ingredient in Mytesi®, is a first-in-class anti-secretory agent with a novel mechanism of action—which we believe may have considerable potential for managing the fluid loss and dehydration that leads to devastating health implications in these patients."

Lisa Conte, Jaguar's President and CEO and Napo's interim CEO, stated, "CDD and SBS patients who survive after birth face devastating, lifelong morbidity and a significantly diminished quality of life—including a lifelong need for feeding tubes. We believe Mytesi® may have considerable potential to help manage the severe diarrhea and dehydration symptomatic of CDD and SBS and thus reduce the associated morbidity and mortality, with the added goal of lessening the need for parenteral nutrition. We're grateful for the existence of the orphan drug designation regulatory pathway, which may allow us to receive approval for Mytesi® to address these important and grievous unmet medical needs in small populations of pediatric and youthful patients, while we simultaneously pursue approval of Mytesi® for use in the large populations of patients suffering from chemotherapy-induced diarrhea (CID), irritable bowel syndrome, and inflammatory bowel disease. In a similar fashion, Jaguar's focus on MUMS (Minor Use and Minor Species) indications for Canalevia ™ for CID in dogs and exercise-induced diarrhea (EID) in dogs complements Jaguar's collaboration with Elanco US Inc. on the global development of Canalevia ™ for treatment of diarrhea in the general dog population and other companion animals."

Napo holds global unencumbered rights to key indications for Mytesi®, and is continuing development of Mytesi® for other antidiarrheal indications, with investigational studies completed in irritable bowel syndrome, cholera, traveler's diarrhea, and in pediatric patients, and two planned investigator-initiated trials of the product in breast cancer patients suffering from CID.

About Mytesi®

Mytesi® (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi® is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi®. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

More information and complete Prescribing Information are available at Mytesi.com. Crofelemer, the active ingredient in Mytesi®, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

As previously announced, Jaguar has already received MUMS designation for Canalevia ™ for use in dogs with CID, which Jaguar expects will be the first indication available commercially in Q1, 2018. Canalevia is Jaguar's lead drug product candidate, under investigation for various types 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. Numerous animal and human clinical trials have shown significant beneficial results in the use of crofelemer in the treatment of secretory diarrhea.

"If we are successful in obtaining MUMS designation for Canalevia ™ for use in dogs with EID, it is our hope that this could lead to access to Canalevia ™, under conditional approval, for dogs for this indication also within a year," Conte added.

Proposed Merger

As announced March 31, 2017, Napo and Jaguar have entered a definitive merger agreement. Napo and Jaguar are in the process of evaluating potential follow-on indications for Mytesi® as part of the anticipated combination of the product pipelines of the two companies and an S-4/A was filed with the SEC on May 26, 2017.

The proposed merger of Jaguar and Napo remains subject to customary conditions to closing. Upon the consummation of the merger, Jaguar's name will be changed to Jaguar Health, Inc., and Napo will operate as a wholly-owned subsidiary of Jaguar, focused on human health. As previously stated, Jaguar and Napo expect the merger to close by the end of July 2017.

About Napo Pharmaceuticals, Inc.

San Francisco-based Napo Pharmaceuticals, Inc. focuses on the development and commercialization of proprietary pharmaceuticals for the global marketplace in collaboration with local partners.

For more information, please visit www.napopharma.com.

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. Equilevia ™ (formerly referred to as SB-300) is Jaguar's prescription drug product candidate for the treatment of gastrointestinal ulcers in horses. Canalevia ™ and Equilevia ™ contain ingredients isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Neonorm ™ Calf and Neonorm ™ Foal are Jaguar'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 Equilevia ™ in horses, and Canalevia ™ for cats and dogs.

For more information about Jaguar, please visit www.jaguaranimalhealth.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the commercial availability of Canalevia ™ for use in dogs with CID and EID, possible MUMS designation of Canalevia ™ for use in dogs with EID, the potential of Mytesi® for reducing morbidity and mortality in patients suffering from CDDs and SBS, the development, approval and sales of potential follow-on indications of Mytesi®, the proposed merger between Jaguar and Napo, the expectation that the proposed merger will close by the end of July 2017, Jaguar's intention to develop species-specific formulations of Neonorm ™ in additional target species, and Jaguar'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.

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