

# Jaguar Animal Health and Napo Pharmaceuticals Appoint Dr. Pravin Chaturvedi to Chair Scientific Advisory Board

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## Jaguar and Napo Comment on Potential Follow-on Indications for Mytesi, Napo's "Pipeline Within a Product"

SAN FRANCISCO--(BUSINESS WIRE)--May 10, 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 the appointment of Dr. Pravin Chaturvedi, a highly experienced drug development veteran who has spent more than 25 years in the pharmaceutical/biotech industry, as Chair of the combined company's Scientific Advisory Board, following the expected close of the proposed merger of Jaguar and Napo. Dr. Chaturvedi has served as Chair of Napo's Scientific Advisory Board since March 27, 2017. Dr. Chaturvedi is responsible for providing direction on strategy, tactics and oversight regarding advancing the development and commercialization of the companies' drug pipelines, including, but not limited to, Mytesi <sup>®</sup> and SB-300.

From 2006 to 2013, Dr. Chaturvedi served as Napo's Chief Scientific Officer and has remained a scientific adviser to the company since 2014. His track record of successful development includes participating in and/or leading development efforts for seven drugs, including Napo's Mytesi <sup>®</sup> (crofelemer) product, which is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. For this indication, Dr. Chaturvedi led the key opinion leader efforts that contributed to the successful use of adaptive clinical trial design for the Mytesi<sup>®</sup> pivotal trial and its approval by the FDA.

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<sup>®</sup> as part of the anticipated combination of the product pipelines of the two companies. Dr. Chaturvedi is chairing the investigation of Mytesi<sup>®</sup> for possible follow-on indications, which include chemotherapy-induced diarrhea, irritable bowel syndrome (IBS), for which proof of concept data is already in hand, inflammatory bowel diseases (IBD) and diarrhea resulting from hospital-acquired infections such as *Clostridium difficile*, a bacterium that is the most common cause of infectious diarrhea in hospital settings.

Napo recently convened a Scientific Advisory Board meeting with expert gastroenterologists, who provided advice on study populations and designs in IBS and IBD. As Douglas Drossman, MD, Professor Emeritus at the University of North Carolina, who is a gastroenterologist in private practice at Drossman Gastroenterology, noted, "The safety profile of crofelemer constitutes an advantage that differentiates it from many other gastrointestinal products."

Mytesi<sup>®</sup> is also being explored for treatment of important orphan gastrointestinal indications such as congenital diarrheal disorders (CDD) and diarrhea associated with short-bowel syndrome (SBS). CDDs are a group of rare, chronic intestinal channel diseases characterized by large, watery stools containing an excess of chloride and sodium, lifelong diarrhea, and a lifelong need for nutritional intake with a feeding tube. CDDs are related to specific genetic defects inherited as autosomal recessive traits, and the incidence of CCDs is much more prevalent in regions where consanguineous marriage is part of the culture.

Patients with SBS are born with a substantial shortening of the small intestine, to a mean length of 50 cm, compared with a normal length at birth of 190-280 cm. This could be due to either a genetic disorder or pre-mature birth. In regions such as the United Arab Emirates and Saudi Arabia, both CDD and SBS occur with much higher incidence. Napo has 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.

Dr. Chaturvedi is also providing oversight for development of Napo's proprietary second-generation anti-secretory agent for cholera—a possible indication that may present Napo with an opportunity for an FDA tropical disease priority review voucher. Under FDA regulations, the sponsor of a human drug application for a qualified tropical disease may be eligible for a priority review voucher, which can be used to obtain priority review for any subsequent human drug application submitted to FDA. These vouchers, which are transferable, have recently sold for \$125 million - \$350 million, and provide an immediate return on investment for the development of a novel product for important indications.

"I am thrilled to be supporting Napo's and Jaguar's shared mission to change the global standard of care for gastrointestinal diseases," stated Dr. Chaturvedi. "I look forward to evaluating potential multiple follow-on gastrointestinal indications for Mytesi<sup>®</sup>, and leveraging the collective expertise of

our team in advancing drug development through innovative approaches such as the adaptive clinical trial design that led to the FDA approval of Mytesi<sup>®</sup> for its current indication of treating noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy."

"We are very pleased that Dr. Chaturvedi has returned to support these principal development activities," Conte commented, "which, if approved, will complement our current sales of Mytesi<sup>®</sup> for noninfectious diarrhea in adult HIV/AIDS patients on antiretroviral therapy. We consider Mytesi<sup>®</sup> a 'pipeline within a product', and Napo has global unencumbered rights to this novel first-in-class anti-secretory agent with multiple potential follow-on indications."

Dr. Chaturvedi has co-founded and led multiple biotech enterprises including Scion, IndUS and Oceanyx, and has served as the CEO or CSO for Scion, IndUS, Napo, and Oceanyx and is the CEO for Pivot Pharmaceuticals. Over his career, Dr. Chaturvedi led discovery and/or development activities for several new chemical entities (NCEs) and has participated in the discovery and/or development of novel drugs for treatment of HIV, hepatitis C, epilepsy and Alzheimer's disease. Earlier in his career, Dr. Chaturvedi was head of lead evaluation at Vertex Pharmaceuticals and was in the preclinical group at Alkermes. He started his career in the product development group at Parke-Davis/Warner-Lambert Company (now Pfizer). Dr. Chaturvedi holds a Ph.D. in Pharmaceutical Sciences from West Virginia University and a Bachelor's in Pharmacy from the University of Bombay.

## **Proposed Merger**

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. Subject to the conditions to closing, the proposed merger is expected to close by the end of July 2017.

# About Mytesi®

Mytesi<sup>®</sup> (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi<sup>®</sup> is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi<sup>®</sup>. 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 <u>Mytesi.com</u>. Crofelemer, the active ingredient in Mytesi<sup>®</sup>, is a botanical (plantbased) 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.

## 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 <u>www.napopharma.com</u>.

#### 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 <sup>TM</sup> is Jaguar's lead prescription drug product candidate, intended for the treatment of various forms of diarrhea in dogs. Equilevia <sup>TM</sup> (formerly referred to as SB-300) is Jaguar's prescription drug product candidate for the treatment of gastrointestinal ulcers in horses. Canalevia <sup>TM</sup> and Equilevia <sup>TM</sup> contain ingredients isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Neonorm <sup>TM</sup> Calf and Neonorm <sup>TM</sup> Foal are the Company's lead non-prescription products. Neonorm <sup>TM</sup> is a standardized botanical extract derived from the *Croton lechleri* tree. Canalevia <sup>TM</sup> and Neonorm <sup>TM</sup> 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 <sup>TM</sup> in six additional target species, formulations of Equilevia <sup>TM</sup> in horses, and Canalevia <sup>TM</sup> 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 development, approval and sales of potential follow-on indications of Mytesi<sup>®</sup>, the proposed merger between Jaguar and Napo, Jaguar's intention to develop species-specific formulations of Neonorm <sup>™</sup> in additional target species, and the Company's plan to develop formulations of Canalevia <sup>™</sup> 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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