

Jaguar Health Subsidiary Napo Pharmaceuticals Issues Further Regulatory Update Regarding Potential Follow-on Indication for Mytesi

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SAN FRANSISCO, CA / ACCESSWIRE / April 2, 2019 / Napo Pharmaceuticals, Inc. (Napo), a human health company developing and commercializing novel gastrointestinal prescription products from plants used traditionally in rainforest areas, and a wholly-owned subsidiary of Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company"), a commercial stage pharmaceutical company focused on developing novel, sustainably derived gastrointestinal products on a global basis, issued the following updates today regarding the Company's March 28, 2019 meeting with the U.S. Food & Drug Administration (FDA) to review the protocol for Napo's planned Phase 3 clinical trial in cancer subjects to evaluate the effects of Mytesi® (crofelemer) in prevention and/or relief of cancer therapy-related diarrhea (CTD).

Participants in the meeting, which was with the FDA's Division of Gastroenterology and Inborn Errors Products, included Pravin Chaturvedi, Ph.D., Napo's/Jaguar's Chairman of the Scientific Advisory Board (SAB) and Acting Chief Scientific Officer, regulatory affairs, medical safety monitoring, and biostatistics specialists, and academic key opinion leaders (KOLs)/SAB members from leading oncology treatment institutions, one of whom will serve as the Principal Investigator (PI) for the Company's planned trial. The meeting also included representatives from the FDA's Division of Oncology Products I and Office of Biostatistics/Division of Biometrics III.

"We had a very collaborative discussion about the clinical trial design that would allow the determination of safety and efficacy of crofelemer in CTD," Dr. Chaturvedi, stated. "We certainly came away with a better understanding of the FDA's focus on the unmet medical needs of cancer patients specifically related to diarrheal episodes that interfere with patient quality of life as well as the ability to provide adequate dosing of cancer therapy regimens. Napo's planned next step is to continue its interactions with the FDA and incorporate the input from this dialog into the Phase 3 protocol following this very informative discussion."

A significant proportion of patients undergoing cancer therapy experience diarrhea. Novel targeted cancer therapy agents, such as epidermal growth factor receptor antibodies and tyrosine kinase inhibitors, with or without cycle chemotherapy agents, may activate intestinal chloride secretory pathways leading to increased chloride secretion into the gut lumen, coupled with significant loss of water, that would result in secretory diarrhea.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas. Our 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.

For more information about Jaguar, please visit <u>jaguar.health</u>. For more information about Napo, visit <u>napopharma.com</u>.

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%).

See full Prescribing Information 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.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that the Company will conduct a Phase 3 clinical trial in cancer subjects to evaluate the effects of crofelemer in prevention and/or relief of CTD, the expectation that one of the KOLs/SAB members who participated in the March 28, 2019 meeting with the FDA will serve as the PI for the planned trial, and the expectation that Napo will continue interactions with the FDA. 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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