Napo Pharmaceuticals Presents New Data at the 13th International Conference on HIV Treatment and Prevention Adherence Regarding the Use of Mytesi (Crofelemer) to Treat Noninfectious Diarrhea in HIV Patients

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The presentation reported the findings on measures of physical and social function as well as work productivity, which revealed statistically significant improvements in several of the measures

SAN FRANCISCO, CA / ACCESSWIRE / June 12, 2018 / 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), announced today the presentation of the data from the long-term Phase 3 trial (ADVENT) of Mytesi® (crofelemer) in patients with HIV-related diarrhea. The ADVENT study was a multicenter, randomized, placebo-controlled trial that enrolled 274 patients treated with either Mytesi 125mg bid or placebo. The presentation reported the findings on measures of physical and social function as well as work productivity, which revealed statistically significant improvements in several of the measures at four weeks, and sustained improvement over six months. The results were reported at Adherence 2018 (the 13th International Conference on HIV Treatment and Prevention Adherence), which took place June 8-10, 2018 at the Loews Miami Beach Hotel in Miami.

Mytesi (crofelemer) is the only drug that has been specifically studied in and FDA-approved for use in managing non-infectious diarrhea in people living with HIV. The primary efficacy and safety results from ADVENT have previously been reported, with more than twice as many patients on crofelemer compared to placebo achieving a response of ≤2 watery stools per week in 4 weeks ($p<0.01$), and 56% of crofelemer-treated patients achieving this response by 24 weeks. The results of this analysis of functional measures include, for example, a 21% reduction in activity impairment over the 24-week trial in all crofelemer-treated patients.

"Chronic persistent diarrhea is a problem that affects 1 in 5 people living with HIV. This study suggests that treatment for diarrhea in this group of patients had a positive effect on their physical and social activity as well as work productivity," commented Patrick G. Clay, PharmD, FCCP, CCTI, consultant pharmacologist for FDA and professor of pharmacy practice at the University of North Texas System College of Pharmacy. "No longer does diarrhea have to take a toll on our HIV patients."

The measures, which were included in the statistical analysis plan of the ADVENT trial, included the SF36v2 survey instrument and the WPAI: SHP (Work Productivity and Activity Impairment Questionnaire). These are validated instruments that measure physical and social functioning, general and emotional health, and work productivity and activity. At the end of the four weeks of the placebo-controlled portion of the study, improvements in nine of the ten domains in the SF36v2 and in three of the four WPAI: SHP domains were documented.

"Diarrhea has long affected the lives of people living with HIV in innumerable ways. It is also a problem that we believe will become more widespread as the HIV+ population ages. According to the U.S. Centers for Disease Control and Prevention, by 2020 more than 70 percent of Americans with HIV are expected to be age 50 or older," said Lisa Conte, Jaguar's president and CEO. "Additionally, diarrhea is known to affect patient adherence to ART regimens. Expanding awareness in the HIV community that a treatment is available for HIV-related diarrhea remains an area of high need."

Launched by Napo in October 2016, Mytesi is the only antidiarrheal studied in and U.S. FDA-approved for the symptomatic relief of noninfectious diarrhea in adults living with HIV/AIDS on antiretroviral therapy (ART). Mytesi is a prescription treatment for diarrhea that works differently, by acting locally in the GI tract to normalize the flow of water. Mytesi does not have any clinically relevant drug-drug interactions and has side effects that are similar to placebo.

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.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage natural-products 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 jaguar.health. For more information about Napo, visit napopharma.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the belief of Napo and Jaguar that chronic diarrhea will become more widespread as the U.S. HIV+ population ages. 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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