



## **Jaguar Subsidiary Napo Pharmaceuticals Files CMC Supplement with FDA for Sample-Size Bottles of Mytesi, Napo's FDA-Approved Human Drug, to Support Upcoming National Sample Campaign**

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SAN FRANCISCO--(BUSINESS WIRE)--Sep. 28, 2017-- Jaguar Health, Inc. (NASDAQ: JAGX) (Jaguar), a natural-products pharmaceuticals company focused on developing and commercializing novel, sustainably-derived gastrointestinal products for both human prescription use and veterinary use on a global basis, announced today that its wholly-owned subsidiary, Napo Pharmaceuticals, Inc. (Napo), has filed a Chemistry, Manufacturing, and Controls (CMC) supplement with the U.S. Food & Drug Administration (FDA) for six-tablet bottles of Mytesi<sup>®</sup>, Napo's FDA-approved human drug, in preparation for Napo's planned national sample campaign.

Mytesi<sup>®</sup> is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Jaguar and Napo are pursuing a follow-on indication for Mytesi<sup>®</sup> in chemotherapy-induced diarrhea (CID), an important supportive care indication for patients undergoing primary or adjuvant chemotherapy for cancer treatment. Mytesi<sup>®</sup> is also in development for rare disease indications for infants and children with congenital diarrheal disorders and short bowel syndrome (SBS); for irritable bowel syndrome (IBS) (Mytesi<sup>®</sup> has demonstrated benefit to IBS-D patients in published Phase 2 studies); for supportive care for inflammatory bowel disease (IBD); and as a second-generation anti-secretory agent for use in cholera patients. Mytesi<sup>®</sup> has received orphan-drug designation for SBS.

The planned sample bottles will contain enough Mytesi<sup>®</sup> tablets for three days of use. To implement the filing, Napo produced stability data in support of a one-year shelf life for the contents of the sample bottles.

As announced earlier this month, Napo significantly expanded the national salesforce for Mytesi<sup>®</sup> through the recent hire in key U.S. markets of six sales representatives experienced in the sale of drugs to HIV physicians and gastroenterologists. Napo's new sales representatives are based in and will cover New York, Miami, Atlanta, Los Angeles, Houston, San Francisco and the surrounding regions. A dedicated Mytesi<sup>®</sup> salesperson has been based in the St. Louis/Chicago area since this past March. All of these regions are key markets for HIV-related drug sales.

"Chronic diarrhea remains a significant complaint of people living with HIV/AIDS, particularly those who are older and have lived the virus in their gut for over 10 years. This is a growing demographic of the HIV community, and Mytesi<sup>®</sup> 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," Pete Riojas, Napo's national sales director for Mytesi<sup>®</sup>, stated. "Driving patient awareness about Mytesi<sup>®</sup> is one of our key goals, and we expect our planned sample program to be highly impactful in this regard."

Mytesi<sup>®</sup> is currently covered by Medicaid in all 50 states. It is also currently covered on 100% of the top 10 commercial insurance plans, representing more than 245 million U.S. lives. Additionally, Napo operates a co-pay coupon to ensure that no participating patients have a Mytesi<sup>®</sup> co-pay greater than \$25. Information about the NapoCares Patient Assistance Program, which assists patients with benefit verification, prior authorization, and claims appeals, can be found at [mytesi.com/mytesi-savings.html](http://mytesi.com/mytesi-savings.html).

### **About Mytesi<sup>®</sup>**

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 [Mytesi.com](http://Mytesi.com). Crofelemer, the active ingredient in Mytesi<sup>®</sup>, 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 natural-products pharmaceuticals company focused on developing and commercializing novel, sustainably derived gastrointestinal products for both human prescription use and animals 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<sup>®</sup> (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. Mytesi<sup>®</sup> is in development for multiple possible follow-on indications, including chemotherapy-induced diarrhea; orphan-drug indications for infants and children with congenital diarrheal disorders and short bowel syndrome; supportive care for inflammatory bowel disease (IBD); irritable bowel syndrome (IBS); and as a second-generation anti-secretory agent for use in cholera patients. Canalevia<sup>™</sup> is our lead animal prescription drug candidate, intended for treatment of various forms of diarrhea in dogs. Equilevia<sup>™</sup> is Jaguar's non-prescription product for total gut health in equine athletes. Canalevia<sup>™</sup> and Equilevia<sup>™</sup> contain ingredients isolated and purified from the *Croton lechleri* tree, which is sustainably harvested. Neonorm<sup>™</sup> Calf and Neonorm<sup>™</sup> Foal are Jaguar's lead non-prescription animal products. Mytesi<sup>®</sup>, Canalevia<sup>™</sup>, Equilevia<sup>™</sup> and Neonorm<sup>™</sup> are distinct products that act at the same last step in a physiological pathway generally present in mammals.

For more information about Jaguar, please visit [jaguar.health](http://jaguar.health). For more information about Napo, visit [napopharma.com](http://napopharma.com).

### Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that the planned Mytesi<sup>®</sup> sample program will be highly impactful in driving patient awareness about Mytesi<sup>®</sup>, and about the development of potential Mytesi<sup>®</sup> follow-on indications. 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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