

# Jaguar Health Subsidiary Napo Pharmaceuticals Completes Filing of Investigational New Drug Application for Crofelemer (Mytesi) for Symptomatic Relief of Cancer Therapy-Related Diarrhea

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SAN FRANCISCO, CA / ACCESSWIRE / July 6, 2020 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") announced today that the Company's wholly owned subsidiary Napo Pharmaceuticals, Inc. ("Napo") has completed the filing of the investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) for crofelemer (Mytesi<sup>®</sup>) for the planned indication of prophylaxis and symptomatic relief of diarrhea in adult patients with solid tumors receiving targeted therapy with or without standard chemotherapy ("cancer therapy-related diarrhea" (CTD)).

A significant proportion of patients undergoing cancer therapy experience diarrhea. Novel "targeted cancer therapy" agents, such as epidermal growth factor receptor (EGFR) antibodies and tyrosine kinase inhibitors (TKIs), with or without cycle chemotherapy agents, may activate intestinal chloride ion channel-mediated secretory pathways leading to increased electrolyte and fluid content in the gut lumen, which results in passage of loose/watery stools, i.e. secretory diarrhea.

"Many cancer patients on targeted therapy require drug holidays or dose reductions in their therapy due to diarrhea," Lisa Conte, Jaguar's president and CEO, stated. "Reducing frequency of watery stools will provide symptomatic relief of diarrhea and should allow better adherence to the therapeutic dosing of any targeted therapies, potentially leading to better clinical outcomes. We have learned from business development discussions with cancer drug manufacturers that adoption and continued use of targeted cancer therapies is directly related to the ability of patients to tolerate use of the therapies - highlighting the importance of supportive care drugs like Mytesi to help manage cancer treatment-related diarrhea in this patient population."

Mytesi, a novel non-opiate, plant-based, chloride ion channel modulating antidiarrheal medicine, is currently commercialized for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. Crofelemer, the active ingredient in Mytesi, comes from the *Croton lechleri* tree, which is responsibly and sustainably harvested in South America.

# About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, sustainably derived gastrointestinal products on a global basis. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based 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 and the only oral plant-based prescription medicine approved under FDA Botanical Guidance.

For more information about Jaguar, please visit https://jaguar.health. For more information about Napo, visit www.napopharma.com.

### About Mytesi<sup>®</sup>

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 <u>Mytesi.com</u>. 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 development of crofelemer for the potential additional indication of symptomatic relief of CTD, and the expectation that reducing frequency of watery stools in cancer patients will allow better adherence to the therapeutic dosing of any targeted therapies, potentially leading to better clinical outcomes. 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. Some of the factors that could affect our actual results are included in the periodic reports on Form 10-K and Form 10-Q that we file with the Securities and Exchange Commission. 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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