



## Jaguar Health Announces Activation of Investigational New Drug (IND) for Crofelemer (Mytesi) for Prophylaxis and Symptomatic Relief of Cancer Therapy-Related Diarrhea

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### *A significant proportion of patients undergoing cancer therapy experience diarrhea*

**SAN FRANCISCO, CA / ACCESSWIRE / August 6, 2020 /** Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") announced today the activation of the investigational new drug (IND) application filed by the Company's wholly owned subsidiary Napo Pharmaceuticals, Inc. ("Napo") with the U.S. Food and Drug Administration (FDA) for the use of crofelemer (Mytesi®) for 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)). Activation of this IND is a key milestone for Napo to initiate its pivotal trial with Mytesi in CTD in adult solid tumor patients.

"We are very pleased that Napo's IND for CTD is now active," Lisa Conte, Jaguar's president and CEO, stated. "Many cancer patients on targeted therapy require drug holidays or dose reductions in their therapy due to diarrhea. Reducing frequency of watery stools will provide symptomatic relief of diarrhea and may allow better adherence to the therapeutic dosing of targeted therapies and/or chemotherapy, potentially leading to better clinical outcomes. In addition to tumor burden reduction, the adoption and/or continued use of targeted cancer therapies is also related to the ability of patients to tolerate their cancer therapies - highlighting the potential importance of Mytesi to help manage cancer treatment-related diarrhea in this patient population. Our planned study for diarrhea related to CTD will use the same formulation and dosing that is used for the current commercialized Mytesi for the symptomatic relief of HIV/AIDS associated diarrhea in adult patients receiving antiretroviral therapy."

According to the Centers for Disease Control and Prevention (CDC), approximately 650,000 cancer patients in the U.S. receive chemotherapy in an outpatient oncology clinic each year. A significant proportion of patients undergoing cancer therapy experience diarrhea, and diarrhea has the potential to cause dehydration, potential infections, and non-adherence to treatment in this population.

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). Diarrhea has been reported as one of the most common side effects of TKIs, including the recently approved irreversible pan-HER TKI neratinib (Nerlynx®), with occurrence ranging from 86% to >95% in published studies. Diarrhea is also a common side effect of some CDK 4/6 inhibitors.

The Company previously announced a preclinical [study](#) evaluating the effects of crofelemer (Mytesi) in providing symptomatic relief of diarrhea associated with neratinib (Nerlynx) at the American Association for Cancer Research Virtual Annual Meeting II, which took place June 22 - 24, 2020. The study was conducted by Napo in collaboration with Puma Biotechnology, Inc. (Puma). Nerlynx, a Puma drug product, is approved for the extended adjuvant treatment of adult patients with early stage HER2 positive breast cancer and for metastatic HER2 positive breast cancer.

Mytesi is a non-opiate, plant-based, chloride ion channel modulating anti-diarrheal medicine that is currently FDA approved for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS receiving antiretroviral therapy. Mytesi has a novel mechanism of action that works locally in the gut by gently and effectively modulating and normalizing the flow of water and electrolytes with minimal systemic absorption.

### **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® (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](http://www.napopharma.com).

### **About Mytesi®**

Mytesi (crofelemer) is an anti-diarrheal 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](http://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 development of crofelemer for the potential additional indication of prophylaxis and symptomatic relief of CTD, and the expectation that reducing frequency of watery stools will allow better adherence to the therapeutic dosing of targeted therapies and/or chemotherapy, 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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