



Jaguar Health Provides Updates on Investigator-Initiated Trials of Crofelemer (Mytesi)

August 19, 2020

Company shares updates on investigator-initiated trials of crofelemer (Mytesi®), a novel FDA-approved plant-based oral prescription medicine

SAN FRANCISCO, CA / ACCESSWIRE / August 19, 2020 / Jaguar Health, Inc. (NASDAQ:JAGX) today provided updates regarding ongoing investigator-initiated trials in non-HIV patient populations of crofelemer (Mytesi®), the novel FDA-approved plant-based oral drug developed and marketed by Jaguar's wholly-owned subsidiary, Napo Pharmaceuticals, Inc.

Updates Regarding Investigator-Initiated Trials:

Chronic Idiopathic Diarrhea in Non-HIV Adult Patients

Yield of Diagnostic Tests and Management of Crofelemer for Chronic Idiopathic Diarrhea in Non-HIV Patients: A Pilot Study

Following COVID-related delays, this single-center clinical research study in adult non-HIV patients at The University of Texas Health Science Center at Houston (UTH) has started enrolling. Full enrollment is expected to be reached by the end of 2020, and the study results are expected to be available by mid to late 2021.

Chronic idiopathic diarrhea is a common complaint of patients presenting to family practitioners and internists and is one of the most common reasons for referral to gastroenterologists. It is estimated that the prevalence of chronic idiopathic diarrhea in developed countries (including the U.S.) is approximately 3-5%. It has a significant negative effect on health-related quality of life and causes a high economic burden on patients and society. The American Gastroenterological Association Burden of Illness study (2012) showed that the estimated annual direct and indirect costs associated with chronic idiopathic diarrhea are up to \$524 million per year and \$136 million per year, respectively.

Functional Diarrhea in Non-HIV Adult Patients

A randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, and efficacy of crofelemer in subjects with functional diarrhea

This investigator-initiated study will be conducted at a single center at Beth Israel Deaconess Medical Center, a Harvard Medical School institution in Boston. This study is expected to initiate enrollment of patients in the fourth quarter of 2020, and topline results are expected to be available in fourth quarter of 2021.

Diarrhea in HER2-positive Breast Cancer Patients

HALT-D: Diarrhea Prevention and Prophylaxis with Crofelemer in HER2 Positive Breast Cancer Patients Receiving Trastuzumab, Pertuzumab, and Docetaxel or Paclitaxel with or without Carboplatin

This is an ongoing investigator-initiated study at Georgetown University to obtain preliminary evidence of the effectiveness of crofelemer for the symptomatic relief of diarrhea in HER2-positive breast cancer patients receiving chemotherapy with trastuzumab, pertuzumab, and docetaxel or paclitaxel with or without carboplatin. The study is nearing completion of enrollment of the full cohort of patients, and subjects in the study are expected to complete treatment by the end of 2020.

The final report for this study is expected to be available in mid-2021.

Mytesi is the only oral plant-based medicine approved by the FDA for the treatment of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy and the only oral plant-based prescription medicine approved under FDA Botanical Guidance. 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. Crofelemer comes from the *Croton lechleri* tree, which is responsibly and sustainably harvested in South America.

SAVE THE DATE:

'Diarrhea Dialogues: Why bowel control is critical to supportive care in cancer,' Educational Event Scheduled for October 20, 2020

Jaguar will host a virtual 'Diarrhea Dialogues: Why bowel control is critical to supportive care in cancer,' educational event for investors and business development contacts on Tuesday, October 20, 2020. Leading oncologists, patient advocates, and supportive care experts will address the importance of supportive care for cancer patients as it relates to chronic lower GI tract distress, specifically with regard to debilitating diarrhea experienced as a

result of cancer therapy. Jaguar will be issuing further details regarding the event, along with information about how investors and business development contacts can register to participate, as we get closer to the October date.

About Jaguar Health, Inc. and Napo Pharmaceuticals, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, specifically chronic, debilitating diarrhea. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals from plants harvested responsibly from 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.

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 related to expectations about when investigator-initiated trials will reach full enrollment, and expectations about the timing of the availability of study reports. 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 several 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.

Contact:

Peter Hodge
Jaguar Health, Inc.
phodge@jaguar.health
Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

accesswire.com

<https://www.accesswire.com/602346/Jaguar-Health-Provides-Updates-on-Investigator-Initiated-Trials-of-Crofelemer-Mytesi>