



Jaguar Health Announces Completion of Investigator-Initiated Phase 2 HALT-D Study Evaluating Mytesi (Crofelemer) for Prevention and Prophylaxis of Diarrhea in Breast Cancer Patients

July 14, 2021

Abstract of study results submitted by the third-party investigators to December 2021 San Antonio Breast Cancer Symposium

SAN FRANCISCO, CA / ACCESSWIRE / July 14, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced that the third-party, investigator-initiated Phase 2 HALT-D study evaluating the effectiveness of Mytesi[®] (crofelemer) for symptomatic relief of diarrhea in HER2 positive breast cancer patients receiving chemotherapy with trastuzumab, pertuzumab, and docetaxel or paclitaxel or trastuzumab, pertuzumab, carboplatin, and docetaxel has been completed. The investigators of the study, which was sponsored by Georgetown University and funded by Genentech, a member of the Roche Group, have submitted an abstract of the results to the San Antonio Breast Cancer Symposium for consideration for presentation at its December 7-10, 2021 [event](#). Per the symposium's regulations, the contents of the abstract or related research, if accepted, are under embargo until the scheduled time of presentation at the event.

"We're very happy that the HALT-D study has been completed," stated Lisa Conte, Jaguar's president and CEO, "and we look forward to the potential acceptance and publication of the study results later this year."

As previously announced, the HALT-D study is separate from the on-going pivotal Phase 3 clinical trial of crofelemer for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy that was initiated in October 2020 by Napo Pharmaceuticals, Jaguar's wholly owned subsidiary.

About Cancer Therapy-related Diarrhea

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 cause increased electrolyte and fluid content in the gut lumen, which results in passage of loose/watery stools (i.e., diarrhea). Diarrhea has been reported as one of the most common side effects of TKIs and may result in cancer therapy drug holidays or reductions from therapeutic dose, potentially impacting patient outcome. Diarrhea is also a common side effect of some approved CDK 4/6 inhibitors.

About Crofelemer

Crofelemer is a botanical (plant-based) drug extracted and purified from the red bark sap, also referred to as "dragon's blood," of the medicinal *Croton lechleri* tree in the Amazon Rainforest. Napo has established a sustainable harvesting program, under fair trade practices, for crofelemer to ensure a high degree of quality, ecological integrity, and support for Indigenous communities. Crofelemer is the active ingredient in Mytesi[®], Jaguar's FDA approved drug to treat diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). It is the only oral plant-based prescription medicine approved under FDA Botanical Guidance.

About Jaguar Health, Inc., Napo Pharmaceuticals, Inc. & Napo EU S.p.A.

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. Napo Pharmaceuticals' wholly owned Italian subsidiary, Napo EU S.p.A., focuses on expanding crofelemer access in Europe.

For more information about Jaguar, please visit <https://jaguar.health>. For more information about Napo Pharmaceuticals, visit www.napopharma.com. For more information about Napo EU, visit www.napoeu.com.

About Mytesi[®]

Mytesi[®] (crofelemer delayed release tablets) 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%).

More information and complete Prescribing Information are available at Mytesi.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the potential acceptance of the study results for publication later this year. 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.

Contact:

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

SOURCE: Jaguar Health, Inc.

accesswire.com

<https://www.accesswire.com/655452/Jaguar-Health-Announces-Completion-of-Investigator-Initiated-Phase-2-HALT-D-Study-Evaluating-Mytesi-Crofelemer-for-Prevention-and-Prophylaxis-of-Diarrhea-in-Breast-Cancer-Patients>