



Jaguar Health Announces that Interim Analysis Requirement Met in Phase 2 HALT-D Study Evaluating Mytesi (Crofelemer) for Prevention and Prophylaxis of Diarrhea in Breast Cancer Patients

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SAN FRANCISCO, CA / ACCESSWIRE / November 14, 2019 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company"), today announced that Georgetown University's Data Safety Monitoring Committee ("DSMC") has reviewed the interim analysis for futility for the third-party, investigator-initiated Phase 2 HALT-D study evaluating the effectiveness of Mytesi[®] (crofelemer) for symptomatic relief in HER2 positive breast cancer patients receiving chemotherapy with trastuzumab, pertuzumab, and docetaxel or paclitaxel or trastuzumab, pertuzumab, carboplatin, and docetaxel (the "Study"). The DSMC has notified the Principal Investigator that the Study is allowed to enroll to completion. Enrollment in the Study now exceeds 85%, and the treatment period for each patient is 3 months.

"We're very pleased to have been informed of the DSMC's decision and to see this important study milestone - 'Positive Interim Results' as defined in the July 2019 Company prospectus - achieved," Lisa Conte, Jaguar's president and CEO commented. "Although this Study is not required to support the clinical program for Mytesi (crofelemer) for FDA approval for cancer therapy-related diarrhea, the final results may inform us about potential exploratory clinical endpoints for our planned Phase 3 clinical study for cancer therapy-related diarrhea and development activities aimed at additional indications for Mytesi."

As previously announced, the protocol for the HALT-D Study is a randomized, 1:1, stratified, open-label phase II study in patients with HER2 positive breast cancer receiving trastuzumab, pertuzumab, and docetaxel or paclitaxel with or without carboplatin in any setting for three cycles. Mytesi (crofelemer) tablets are administered daily at an oral dose of 125 mg twice daily during cycles 1 and 2 of the treatment period. The endpoints to be analyzed are the total number of patients with all grade diarrhea for two or more consecutive days during cycles 1 and 2 and additional exploratory endpoints. The Study, which is sponsored by Georgetown University and funded by Genentech, a member of the Roche Group, called for an interim analysis for futility when the Study enrollment reached 50%. This interim analysis has now been completed and the Georgetown DSMC has indicated to the Principal Investigator that the Study is allowed to enroll to completion.

As recently announced, a preclinical study conducted in female dogs with an FDA-approved tyrosine kinase inhibitor (TKI), showed that Mytesi (crofelemer) treatment resulted in lesser incidence and severity of diarrhea in dogs with the maintenance and tolerability of up to a 20% higher dose of the selected TKI compared to placebo group.

A significant proportion of patients undergoing cancer treatment experience diarrhea as a major dose-limiting side effect. Novel targeted cancer therapy agents, such as epidermal growth factor receptor antibodies and TKIs, with or without standard chemotherapy agents, may activate chloride ion channels that result in increased fluid and electrolyte content in the gastrointestinal lumen, potentially leading to secretory diarrhea.

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.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products 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[®] (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

For more information about Jaguar, please visit jaguar.health. For more information about Napo, visit napopharma.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the belief that reviewing the final results of the Study may inform the Company about potential exploratory clinical endpoints for the Company's planned Phase 3 clinical study for cancer therapy-related diarrhea and development activities aimed at additional indications for Mytesi, and the belief that novel targeted cancer therapy agents, such as epidermal growth factor receptor antibodies and TKIs, with or without standard chemotherapy agents, may activate chloride ion channels that result in increased fluid and electrolyte content in the gastrointestinal lumen, potentially leading to secretory diarrhea. 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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