Jaguar Health Announces the Presentation of Findings from the Investigator-Initiated Phase 2 HALT-D Study of Crofelemer for Prevention of Chemotherapy-Induced Diarrhea (CID) in Breast Cancer Patients at San Antonio Breast Cancer Symposium (SABCS 2021)

December 10, 2021

Results of the study provide the first proof-of-concept data for potential use of crofelemer - a novel, oral, plant-based, non-opioid antidiarrheal prescription medication - in breast cancer patients

SAN FRANCISCO, CA / ACCESSWIRE / December 10, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) and its wholly owned subsidiary Napo Pharmaceuticals today announced the third-party presentation of findings from the investigator-initiated HALT-D trial evaluating crofelemer for preventing chemotherapy-induced diarrhea (CID) in HER2-positive breast cancer patients being treated with trastuzumab, pertuzumab and a taxane. These therapies cause CID in up to 80% of breast cancer patients, reaching grade 3, which often requires hospitalization, in 8-12% of patients. No antidiarrheal medications are currently approved that specifically target the underlying mechanism of CID.

As presented today at SABCS by lead study investigator Paula Pohlmann, MD, PhD, formerly from Georgetown University and now Associate Professor, MD Anderson Cancer Center, HALT-D included 51 breast cancer patients scheduled to receive at least three cycles of chemotherapy and randomly assigned to either crofelemer in cycles 1 and 2 or the control group, which received standard of care. Antidiarrheal medications for breakthrough diarrhea were permitted but not given prophylactically. Findings showed that the primary endpoint, the incidence of diarrhea for at least two consecutive days, was not statistically different for the two groups. However, crofelemer patients demonstrated significantly better outcomes compared to control group patients across a number of key secondary endpoints in incidence and severity of diarrhea in cycle 2 based on Investigator and Patient Reported Outcomes (PRO) as previously reported in the study abstract (see Jaguar Health's November 19, 2021 press release). In the poster presented today, additional findings include that CID occurred significantly less (23%) in the crofelemer group during cycle 1 and crofelemer patients were 1.8 times more likely than control patients to have their diarrhea resolved.

"Our findings show benefits of crofelemer across a range of important diarrhea-related measures, including its incidence, severity and probability of resolving," said Dr. Pohlmann. "The lack of difference in the primary endpoint was due to about 70% of patients in both groups having at least two consecutive days of diarrhea, regardless of cycle or CID treatment group; in fact the typical cancer patient experiences many more days of CID. It is clear that the primary endpoint is not clinically relevant as it does not differentiate the severity nor duration of CID among treatment groups. We are pleased the secondary endpoints provide a more precise assessment of CID, which will guide future studies."

"These important HALT-D findings give us hope that the side effect of diarrhea that often accompanies these very effective chemotherapy regimens for HER2-positive breast cancer can be mitigated and make the treatment more tolerable," said Sandra M. Swain, MD, Associate Dean for Research Development at the Georgetown University Medical Center and the senior investigator of the study. "The findings support further testing of crofelemer in CID, and help identify appropriate endpoints that take into account its frequency and severity, which impacts patients' quality of life and dignity."

Napo Pharmaceuticals and Jaguar Health President and CEO Lisa Conte said, "With more than 44 presentations at SABCS reporting CID as a prevalent side effect in clinical studies that evaluated breast cancer therapies, there is a clear unmet need for prophylactic CID treatment. We are pleased with the HALT-D study results which show the potential benefit of crofelemer, and are also pleased that the results provide important proof of concept data for the potential use of crofelemer in breast cancer patients. We thank both the HALT-D investigators and the patients who participated in this study. Our ongoing phase 3 OnTarget study evaluating crofelemer as a prophylactic treatment for cancer therapy-related diarrhea demonstrates our continued commitment to comprehensive care of cancer patients."

The HALT-D study is separate from the OnTarget study, the pivotal Phase 3 clinical trial of crofelemer for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. OnTarget is sponsored by Napo Pharmaceuticals, Jaguar Health's wholly owned subsidiary. For more information about the OnTarget trial visit clinicaltrials.gov (NCT04538625).

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 novel, oral plant-based medicine purified from the red bark sap, also referred to as "dragon's blood," of the medicinal *Croton lechleri* tree in the Amazon Rainforest. Napo Pharmaceuticals 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.

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. 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 Health, please visit https://jaguar.health. For more information about Napo Pharmaceuticals, visit www.napopharma.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. Infectious etiologies of diarrhea should be ruled out by a physician 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." 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 Health 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 Health's control. Except as required by applicable law, Jaguar Health 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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https://www.accesswire.com/676615/Jaguar-Health-Announces-the-Presentation-of-Findings-from-the-Investigator-Initiated-Phase-2-HALT-D-Study-of-Crofelemer-for-Prevention-of-Chemotherapy-Induced-Diarrhea-CID-in-Breast-Cancer-Patients-at-San-Antonio-Breast-Cancer-Symposium-SABCS-2021