



## **Jaguar Health Announces Publication in Breast Cancer Research and Treatment of Investigator-Initiated Phase 2 HALT-D Study of Crofelemer for Prevention of Chemotherapy-Induced Diarrhea (CID) in Breast Cancer Patients**

October 26, 2022

***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 / October 26, 2022 /** Jaguar Health, Inc. (NASDAQ:JAGX) and its wholly owned subsidiary Napo Pharmaceuticals today announced the publication in the peer reviewed journal [Breast Cancer Research and Treatment](#) of the results of 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.

"Diarrhea is a debilitating side effect that many people experience when undergoing breast cancer treatment that demands research attention," said the study's senior investigator, Sandra M. Swain, MD, professor of medicine at Georgetown University and a member of its Lombardi Comprehensive Cancer Center. "This is one of few studies to explore ways of proactively preventing diarrhea in women undergoing lifesaving treatment for their breast cancer. While we have more work to do, this study revealed important information about the treatment of diarrhea in this particular population."

Crofelemer is currently being evaluated in a prophylactic setting in adult patients with solid tumors receiving targeted therapy in the ongoing phase 3 [OnTarget](#) clinical trial. Completion of enrollment is targeted for the first half of 2023.

Results from the HALT-D study were released previously by the investigators at the San Antonio Breast Cancer Symposium (SABCS 2021) 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.

Funding for the HALT-D study was supported by Genentech, Inc., a member of the Roche group, and crofelemer was provided by Napo Pharmaceuticals.

### **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, Napo Pharmaceuticals, Napo Therapeutics & Jaguar Animal Health**

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, including chronic, debilitating diarrhea. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human pharmaceuticals from plants harvested responsibly from rainforest areas. Our crofelemer drug product candidate is the subject of the [OnTarget](#) study, an ongoing pivotal Phase 3 clinical trial for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.), an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe. Jaguar Animal Health is a tradename of Jaguar Health.

For more information about Jaguar Health, please visit <https://jaguar.health>. For more information about Napo Pharmaceuticals, visit [www.napopharma.com](http://www.napopharma.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 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.

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