



Independent Study Published in Clinical Breast Cancer Shows Activity of Jaguar Health's Crofelemer for Neratinib-induced Diarrhea

August 7, 2023

A significant proportion of patients undergoing cancer therapy experience diarrhea, which has the potential to cause dehydration and non-adherence to cancer treatment regimens

Diarrhea was reported in 95% of neratinib-treated patients in randomized placebo-controlled trial

SAN FRANCISCO, CA / ACCESSWIRE / August 7, 2023 / [Jaguar Health, Inc.](#) (NASDAQ:JAGX) ("Jaguar" or "the Company") announced that the results of an independent pilot phase 2 study of [crofelemer for the management of neratinib-associated diarrhea in patients with HER2+ early-stage breast cancer](#) indicate that crofelemer, the Company's FDA approved drug, may be effective for the management of neratinib-induced diarrhea. The results of the study, which was designed by the study's principal investigator, Jo Chien, MD, and published in the peer-reviewed journal *Clinical Breast Cancer*, are consistent with the results of a preclinical dog study evaluating the effects of crofelemer in improving diarrhea associated with neratinib, a tyrosine kinase inhibitor (TKI), presented at the American Association for Cancer Research Virtual Annual Meeting II in June 2020.

"Seven patients underwent treatment with crofelemer and loperamide in this new study, 5 of whom were able to control diarrhea with crofelemer alone. Though this study involved a small number of patients, the results show activity of crofelemer for the management of neratinib-induced diarrhea, which warrants further investigation of crofelemer for treatment of cancer therapy-related diarrhea (CTD)," said study investigator Hope S. Rugo, MD, Professor of Medicine and Winterhof Family Professor of Breast Oncology, University of California San Francisco Helen Diller Family Comprehensive Cancer Center. Dr. Rugo is a member of the Company's Scientific Advisory Board.

"Targeted therapies are playing an increasing role in the treatment of both metastatic and early stage breast cancer. By mitigating the diarrhea often associated with targeted cancer therapies, patients can potentially achieve greater comfort, adhere better to their cancer therapy, and maintain normal daily activities," said Dr. Chien, Professor of Medicine and Medical Director of Breast Medical Oncology, University of California San Francisco Helen Diller Family Comprehensive Cancer Center.

Board Certified patient advocate Stacey Tinianov, MPH, a member of the Company's Scientific Advisory Board, commented, "My focus as a patient advocate is on the quality of life of people undergoing treatment for cancer. Targeted therapies have transformed the cancer treatment ecosystem, but those additional months and years of survival often come with severe side effects. Comfort and dignity are critical components of cancer care. Diarrhea impacts the comfort and dignity of those on targeted cancer therapies as well as their ability to adhere to their targeted cancer therapy."

This single center, open label trial enrolled patients with Stage 2 to 3 HER2+ breast cancer receiving neratinib in the extended adjuvant setting. One cohort took prophylactic crofelemer 125 mg bid and loperamide in the first 2 cycles, and as needed in the subsequent cycles. The second cohort received escalating doses of neratinib with loperamide. The primary endpoint was incidence of grade ≥ 3 diarrhea in the first 2 cycles.

"Novel therapies are needed to improve tolerability of tyrosine kinase inhibitors (TKIs) such as neratinib and other targeted therapies, and to improve outcomes in cancer patients," said Pravin Chaturvedi, PhD, Jaguar's Chair of the Scientific Advisory Board and Chief Scientific Officer. "While this study had a small number of patients, the results show crofelemer is effective in managing diarrhea in patients receiving neratinib. These results also provide support for the Company's ongoing phase 3 [OnTarget](#) trial evaluating crofelemer for the prophylaxis of diarrhea in adult cancer patients receiving targeted therapy with or without chemotherapy. The OnTarget trial evaluates crofelemer prophylaxis in cancer patients with different tumor types receiving different targeted therapies and recently completed enrollment."

Top line results from the Company's ongoing phase 3 OnTarget clinical trial are expected in late October 2023.

About Cancer Therapy-Related Diarrhea (CTD)

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. Patients with CTD are 40% more likely to discontinue their chemotherapy or targeted therapy than patients without CTD,¹ and the cost of care of CTD patients is estimated to be 2.9 times higher than for patients who are not experiencing CTD.²

About Jaguar Health, Napo Therapeutics & Jaguar Animal Health

Jaguar Health is a commercial stage pharmaceuticals company focused on developing novel, plant-based, sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Our crofelemer drug product 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 Therapeutics, visit napotherapeutics.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that crofelemer may be effective for the management of neratinib-induced diarrhea, and Jaguar's expectation that top line results from the Company's OnTarget clinical trial will be available in late October 2023. 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.

¹ Pablo C. Okhuysen, M.D., The impact of cancer-related diarrhea on changes in cancer therapy patterns: Real world evidence

² Eric Roeland, M.D., FAAHPM, Healthcare utilization and costs associated with cancer-related diarrhea

Contact:

hello@jaguar.health

Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

accesswire.com

<https://www.accesswire.com/772541/Independent-Study-Published-in-Clinical-Breast-Cancer-Shows-Activity-of-Jaguar-Healths-Crofelemer-for-Neratinib-induced-Diarrhea>