



## Significant Positive Results with Jaguar Health's Crofelemer for Cancer Therapy-Related Diarrhea (CTD) in Breast Cancer Patients Presented at San Antonio Breast Cancer Symposium (SABCS)

December 12, 2024

**Adult patients with breast cancer are a prespecified subgroup of the recently conducted phase 3 [OnTarget](#) trial evaluating crofelemer for prophylaxis of CTD**

**The majority of patients in the OnTarget placebo group on abemaciclib and pertuzumab-based therapies required dose reduction or elimination**

**SAN FRANCISCO, CA / ACCESSWIRE / December 12, 2024 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) ("Jaguar") family company [Napo Pharmaceuticals](#) ("Napo") today provided an overview of the data from the poster presentation conducted yesterday, December 11, 2024, at the [San Antonio Breast Cancer Symposium](#) (SABCS) about the recently completed analysis of the prespecified subgroup of adult patients with breast cancer from the Phase 3 [OnTarget](#) trial, which indicates that crofelemer achieved statistically significant results in this subgroup. Patients with breast cancer accounted for 183 of the 287 participants in this unprecedented prophylactic clinical trial recently conducted by Napo for diarrhea in adults with solid tumors receiving targeted therapy with or without standard chemotherapy.**

"In this responder analysis of patients with breast cancer on targeted therapies, crofelemer CTD prophylaxis resulted in a greater proportion of monthly responders of diarrhea improvement compared to placebo," said Lisa Conte, Jaguar's president and CEO. "Overall, crofelemer was significantly more effective than placebo in providing sustained response in breast cancer patients, potentially helping them stay on their cancer therapies. This research underscores the potential of crofelemer for prophylaxis of CTD."

"Diarrhea is a common side effect of targeted therapies and can lead to dose changes, treatment delays, or stopping treatment altogether, all of which can impact patient outcomes," said Pablo C. Okhuysen, MD, FACP, FIDSA, the National Principal Investigator of the OnTarget trial. "The OnTarget study specifically analyzed breast cancer patients receiving crofelemer or a placebo for 12 weeks. Patients reported their diarrhea symptoms, and those with fewer than nine loose stools per week were considered 'responders.' Breast cancer patients receiving crofelemer had significantly better control of diarrhea than those on placebo. Nearly half (47.1%) of crofelemer group patients were responders through 12 weeks, compared to 33.7% of those on placebo."



Photo from the December 11, 2024 poster presentation session at SABCS. From left to right: Pravin Chaturvedi, PhD,

Chair of Napo's Scientific Advisory Board (SAB) and Jaguar's Chief Scientific Officer; Lisa Conte, Jaguar's CEO; Pablo C. Okhuysen, MD, FACP, FIDSA, the lead author of both posters; Dr. Barbara Segarra-Vazquez, a patient advocate from Puerto Rico; Napo SAB member Stacey Tinianov, MPH; and Edna Pacheo, a patient advocate from Puerto Rico

As announced, the content of the poster presentation will serve as the basis of the briefing package Napo plans to submit to the U.S. Food and Drug Administration to request a meeting to discuss possible pathways to make crofelemer available as efficiently as possible to breast cancer patients. Additional analyses of OnTarget prespecified subgroups are ongoing, and Jaguar believes data from additional analyses may result in future submissions to peer-reviewed forums.

A second poster related to the OnTarget trial, looking at the frequency and severity of diarrhea in breast cancer patients on abemaciclib and pertuzumab-based therapies, using data from the placebo group of OnTarget, was also the subject of a poster presentation on December 11, 2024 at SABCS. In the OnTarget study, 135 patients with various cancers received a placebo, and 57% of them had breast cancer.

"Of the total of 183 breast cancer patients in the OnTarget trial, most received abemaciclib or pertuzumab. Among those participating patients treated with abemaciclib, more than 43% had to reduce or terminate their dosing due to diarrhea. Similarly, for patients on pertuzumab-based therapies, all required dose reduction or elimination," Conte said. "These results highlight the significant impact of diarrhea on patients undergoing cancer treatment, especially with certain breast cancer therapies. Real-time reporting from patients showed that diarrhea is often under-recognized but can severely affect treatment. More attention to managing diarrhea could improve quality of life and treatment success in breast cancer patients on targeted therapies."

Pablo C. Okhuysen, MD, FACP, FIDSA, the lead author of both posters, is Professor, Department of Infectious Diseases, Infection Control and Employee Health at The University of Texas MD Anderson Cancer Center in Houston. Other key authors of both posters include Pravin Chaturvedi, PhD, Chair of Napo's Scientific Advisory Board (SAB) and Jaguar's Chief Scientific Officer; Napo SAB member Lee Schwartzberg, M.D., FACP, Chief of Medical Oncology at Renown Health in Reno, Nevada; Napo SAB member Eric Roeland, MD, FAAHPM, FASCO, Associate Professor of Medicine, Division of Hematology/Medical Oncology, School of Medicine, Oregon Health & Science University; Napo SAB member Stacey Tinianov, MPH, a Board Certified Patient Advocate; Napo SAB member Dr. Kelly Shanahan, a former clinician and a metastatic breast cancer patient who is now a full-time independent patient advocate; as well as two key advisors to Napo: Enoch Bortey and James Bolognese.



Photo from the December 11, 2024 poster presentation session at SABCS. From left to right: Lisa Conte, Jaguar's CEO; Pravin Chaturvedi, PhD, Chair of Napo's Scientific Advisory Board (SAB) and Jaguar's Chief Scientific Officer; Gitte Joergensen, Ambassador for Jaguar's patient engagement program; Napo SAB member Stacey Tinianov, MPH;

## and Enoch Bortey, a key advisor to Napo

In addition to participating in both poster presentations with its SAB members at SABCS, and in alignment with Jaguar's core focus on patient comfort, dignity, and cancer supportive care in general, Napo hosted a gathering for patient advocates during SABCS as part of the company's ongoing [patient engagement program](#).

Since 1977, SABCS has been the leading scientific conference for scientists, physicians, clinical investigators, breast care providers, and advocates seeking an exchange of new information in experimental biology, etiology, prevention, diagnosis, and therapy of premalignant breast disease and breast cancer. Based on attendance levels from 2023 SABCS, the symposium organizers anticipated more than 10,000 attendees for this year's event.

### About the Jaguar Health Family of Companies

Jaguar Health, Inc. (Jaguar) is a commercial stage pharmaceuticals company focused on developing novel proprietary prescription medicines sustainably derived from plants from rainforest areas for people and animals with gastrointestinal distress, specifically associated with overactive bowel, which includes symptoms such as chronic debilitating diarrhea, urgency, bowel incontinence, and cramping pain. Jaguar family company Napo Pharmaceuticals (Napo) focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Jaguar family company Napo Therapeutics is an Italian corporation Jaguar established in Milan, Italy in 2021 focused on expanding crofelemer access in Europe and specifically for orphan and/or rare diseases. Jaguar Animal Health is a Jaguar tradename. Magdalena Biosciences, a joint venture formed by Jaguar and Filament Health Corp. that emerged from Jaguar's [Entheogen Therapeutics Initiative](#) (ETI), is focused on developing novel prescription medicines derived from plants for mental health indications.

For more information about:

Jaguar Health, visit <https://jaguar.health>

Napo Pharmaceuticals, visit [www.napopharma.com](http://www.napopharma.com)

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### Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the potential of crofelemer for prophylaxis of CTD, Jaguar's expectations that the content of the poster about the results in breast cancer patients from the OnTarget study will serve as the basis of a briefing package Napo will submit to the U.S. Food and Drug Administration to request a meeting to discuss possible pathways to make crofelemer available as efficiently as possible to breast cancer patients, Jaguar's expectation that data from additional analyses of OnTarget prespecified subgroups may result in future submissions to peer-reviewed forums, and Jaguar's expectation that more attention to managing diarrhea could improve quality of life and treatment success in breast cancer patients on targeted therapies. 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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