



Jaguar Health Meeting with FDA Regarding Results of Phase 3 OnTarget Study

March 27, 2025

The statistically significant responder analysis results for Mytesi® (crofelemer) in the [OnTarget](#) study's prespecified subgroup of patients with breast cancer were the subject of a December 2024 poster presentation at the [San Antonio Breast Cancer Symposium](#)

Late-breaker abstract recently submitted to the [Multinational Association of Supportive Care in Cancer \(MASCC\)](#) shows additional significant results for breast cancer subgroup

The American Cancer Society expects 316,950 new cases of breast cancer diagnosed in women in the US in 2025, and it's estimated that there were 4 million US women with a history of invasive breast cancer in 2022

SAN FRANCISCO, CA / [ACCESS Newswire](#) / March 27, 2025 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) ("Jaguar" or the "Company") family company Napo Pharmaceuticals ("Napo") today announced that the U.S. Food and Drug Administration (FDA) has granted Napo a Type C Meeting in the second quarter of 2025 to discuss the responder analysis in the prespecified subgroup of patients with breast cancer for crofelemer in Napo's Phase 3 OnTarget trial. 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. The American Cancer Society expects 316,950 new cases of breast cancer diagnosed in women in the US in 2025,¹ and it's estimated that there were 4 million US women with a history of invasive breast cancer in 2022.²

Napo recently submitted a late-breaker abstract to MASCC on additional significant results in adult breast cancer patients from the OnTarget study for consideration for presentation at MASCC's June 26-28, [2025 Annual Meeting](#) in Seattle, Washington. The authors include Pravin Chaturvedi, PhD, who is Jaguar's Chief Scientific Officer and Chair of Napo's Scientific Advisory Board, as well as leading oncologists and cancer patient advocates.

"As a cancer patient, having options to manage the side effects of life saving drugs is very important. I believe the published results of crofelemer for the prophylaxis of CTD are very exciting and compelling," said Dr. Kelly Shanahan, a former clinician and a metastatic breast cancer patient who serves on Napo's Scientific Advisory Board (SAB).

"Diarrhea is a common side effect of targeted cancer therapies and can lead to dose changes, treatment delays, or cessation of treatment altogether, all of which can impact patient outcomes. We are very happy to have been granted a meeting with the FDA to review the positive OnTarget results in breast cancer patients and our goal is to discuss the most efficient pathways to make crofelemer - our novel, oral plant-based prescription medicine - available to this patient population for cancer therapy-related diarrhea (CTD)," said Lisa Conte, Jaguar's president and CEO. "In this responder analysis of patients with breast cancer on targeted therapies, crofelemer prophylaxis resulted in a greater proportion of monthly responders of diarrhea improvement compared to placebo. Overall, crofelemer was significantly more effective than placebo in providing sustained response in breast cancer patients."

Members of Napo's SAB are expected to join Jaguar representatives at the FDA meeting in the second quarter of 2025.

As previously announced, the initial top line results from the OnTarget study showed that the multicenter, double-blind, placebo-controlled pivotal clinical trial did not meet its primary endpoint for the prespecified analysis of all tumor types. The subgroup analysis in adult breast cancer patients indicates that crofelemer achieved significant results in this subgroup.

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. Napo's crofelemer is FDA-approved under the brand name Mytesi® for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. 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

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

Visit the *Make Cancer Less Shitty* patient advocacy program on [Bluesky](#), [X](#), [Facebook](#) & [Instagram](#)

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that Napo will meet with the FDA in the second quarter of 2025 to discuss the results of the OnTarget study in breast cancer patients and potential pathways to bring crofelemer to this patient population as efficiently as possible for treatment of CTD. 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 several 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 [Cancer Facts & Figures 2025](#), American Cancer Society

² Miller KD, Siegel RL, Lin CC, et al. Cancer treatment and survivorship statistics, 2022. *CA Cancer J Clin.* 2022;1-23

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