



A Majority of Subjects in Jaguar Health's Placebo-Controlled Pivotal Phase 3 OnTarget Trial for Prophylaxis of Diarrhea in Adult Cancer Patients Receiving Targeted Therapy Chose to Continue on to Stage II

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Stage II completed; comprehensive results expected in Q1 2024; company's planned regulatory pathway for FDA approval remains on track

Cancer patients at patient advocacy events voice strong support for company's focus on patient quality of life and the highly neglected need for new therapies for cancer therapy-related diarrhea

SAN FRANCISCO, CA / ACCESSWIRE / December 11, 2023 / [Napo Pharmaceuticals](#) (Napo), a [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) (Jaguar) family company, today announced that a majority of subjects in the company's placebo-controlled pivotal Phase 3 [OnTarget](#) trial for prophylaxis (prevention) of diarrhea in adult cancer patients receiving targeted therapy with or without standard chemotherapy chose to continue on to Stage II of the two-stage trial.

After completing the Stage I double-blind, placebo-controlled primary prophylactic treatment phase of OnTarget, subjects had the option to remain on their blinded assigned treatment arm and re-consent to enter into the Stage II extension phase.

"We are very pleased that a majority of subjects chose to continue on to Stage II while recognizing that their requirement to remain blinded would continue," said Lisa Conte, Jaguar's president and CEO. "We are deeply committed to all patients who participated in the OnTarget trial. We view them as key stakeholders and we thank them for their support and participation in this study."

Stage II of the trial has concluded. Inclusion of Stage I data and Stage II data, with success, is required in the supplemental NDA filing of crofelemer to add the indication for prophylaxis of diarrhea in cancer patients receiving targeted therapy with or without standard chemotherapy.

"Since all patient data will be included in the final locked database, we will remain blinded and will announce the comprehensive results of the full trial, including Stage II results, rather than proceeding with the original plan of announcing top line results for Stage I only. We expect the full trial results to be available in the first quarter of 2024," Conte said. "The clinical trial database includes patients with multiple solid tumor types, and the trial allowed the inclusion of 24 different targeted therapies, including multiple important mechanisms of action for targeted therapy drugs."

OnTarget is a first-of-its-kind, 24-week (two 12-week stages) clinical trial with a primary endpoint based on patient-reported outcomes that address the highly neglected and unmet burden of cancer therapy-related diarrhea, an indication Napo also refers to as preventive treatment of chemotherapy-induced overactive bowel (CIOB) - which includes symptoms such as chronic and/or episodic debilitating diarrhea (loose and/or watery stools), urgency, bowel incontinence and abdominal pain and discomfort.

Diarrhea is a common side effect of targeted therapies and new treatments are needed. Up to 95% of patients on tyrosine kinase inhibitors (TKIs) suffer from diarrhea, depending on the TKI used.¹ The OnTarget study is testing whether the company's plant-based prescription drug crofelemer (versus placebo) can prevent (or substantially reduce) diarrhea and other symptoms of CIOB when any one of the selected 24 different targeted therapies (that are associated with diarrhea in at least 50% of patients) is initiated.

"We are excited as any stakeholder to see the results. We own the expectation we set that data would be available in November 2023. We have to respect and abide by the requirements and Standard Operating Procedures of our third-party service providers and work with them as we meet GCP (Good Clinical Practice) requirements, particularly when conducting a complex global Phase 3 clinical trial," Conte said. "These service providers have important quality control procedures that take time and somewhat expand as the data analysis process progresses. We are working with all vendors that are critical to ensure the integrity of the data. Jaguar and Napo personnel continue to remain blinded to the study results at this time."

Napo's abstract outlining the design of the OnTarget trial, the importance of patient reported outcomes, and the neglected medical need of CIOB was the subject of a poster presentation on December 7, 2023 at the [San Antonio Breast Cancer Symposium](#) (SABCS). More than two dozen leading patient advocacy groups provided powerful voices at events hosted by Napo, highlighting the neglected need of mitigating diarrhea in patients receiving cancer therapies, and expressing strong support for the company's focus on patient quality of life.

About Crofelemer

Crofelemer is the only oral prescription drug approved under FDA botanical guidance. It is plant-based, extracted and purified from the red bark sap of the *Croton lechleri* tree in the Amazon rainforest. Jaguar family company 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 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, and bowel incontinence. Jaguar family company Napo Pharmaceuticals focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo Pharmaceuticals' crofelemer drug product candidate is the subject of the [OnTarget](#) study, a pivotal Phase 3 clinical trial for preventive treatment of chemotherapy-induced overactive bowel (CIOB) in adults with cancer on targeted 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 Jaguar on LinkedIn: <https://www.linkedin.com/company/jaguar-health/>

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Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that the full results of the OnTarget trial will be available in the first quarter of 2024. 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 Moschen AR, Sammy Y, Marjenberg Z, Heptinstall AB, Pooley N, Marczewska AM. The Underestimated and Overlooked Burden of Diarrhea and Constipation in Cancer Patients. *Curr Oncol Rep.* 2022;24(7):861-874. doi:10.1007/s11912-022-01267-3

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