



Jaguar Health to Report Pivotal Phase 3 OnTarget Trial Results for its Cancer Supportive Care Drug Crofelemer on or Before July 23, 2024

June 12, 2024

Investor webcast on or before July 23 will include updates on Jaguar's cancer supportive care portfolio, including participation from Jaguar scientific team, patient advocates, and leading oncology experts on cancer therapy-related diarrhea (CTD) and oral mucositis

Cancer patients with diarrhea are 40% more likely to discontinue their therapy, and up to 40% of cancer patients experience the painful side effect of oral mucositis

SAN FRANCISCO, CA / ACCESSWIRE / June 12, 2024 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) ("Jaguar") today announced that it will hold an investor webcast on or before July 23, 2024 to provide results for the company's pivotal phase 3 [OnTarget](#) trial of crofelemer for prophylaxis of diarrhea in adult cancer patients with solid tumors receiving targeted therapy, with or without standard chemotherapy. The webcast, which will provide updates on Jaguar's advancing cancer supportive care portfolio, will include members of Jaguar's scientific team, patient advocates, and leading oncology experts on two of the most common and intolerable side effects of cancer therapy: CTD and oral mucositis.

"Patients are the heart of our mission at Jaguar," said Lisa Conte, the company's president and CEO. "The thorough and exhaustive OnTarget prophylactic protocol allowed for the inclusion of all treatment needs for participating patients with solid tumors and targeted therapy, including any supportive care. We look forward to receiving and providing the results with the anticipation we know all our stakeholders share. As with many pharmaceutical companies involved with an expansive global pivotal study, we use several third-party contractors. In order to address the complexity of OnTarget's statistical programming needs - as the trial involves multiple solid tumor types, 23 targeted therapies, six countries, daily patient-reported outcomes covering anywhere from 90 to 180 days with multiple entries a day, and concomitant medications - we retained a clinically experienced biostatistics and programming expert to review and lead the statistical programming and the implementation of the statistical analysis plan submitted to the FDA. The third-party vendors who are conducting the analysis of patient data for the OnTarget trial have identified the key necessary steps required to share results with Jaguar on or before July 23, allowing us to set a date for the findings."

"While cancer treatments have advanced considerably since the advent and availability of targeted therapies, significant short- and long-term treatment side effects can be challenging or even devastating to an individual's quality of life," said Stacey Tinianov, 11-year cancer survivor and founder of Advocates for Collaborative Education who serves on the company's Scientific Advisory Board. "Supportive care during treatment is crucial for maintaining dignity and well-being. No side effect, whether extreme fatigue, severe diarrhea, mouth sores, chronic pain, or anything else, should ever be considered 'acceptable' or 'tolerable.'"

In addition to the forthcoming OnTarget data, the following advances in Jaguar's cancer supportive care portfolio will be discussed during the webcast on or before July 23:

- In April 2024, Jaguar entered into an exclusive 5-year U.S. in-license [agreement](#) for the FDA-approved oral mucositis prescription product, Gelclair[®]. Jaguar's promotion of Gelclair began at this year's [Oncology Nursing Society \(ONS\) Congress](#) and the [American Society of Clinical Oncology \(ASCO\) Annual Meeting](#).
- In March 2024, Jaguar signed a binding [term sheet](#) with Turkish specialty pharmaceutical company [GEN](#) related to the commercialization of crofelemer in Turkey and eight neighboring countries following GEN's receipt of regulatory approval for crofelemer for specified indications, including CTD.
- In December 2023 and April 2024, Jaguar supported the patient led advocacy program - "[Make Cancer Less Shitty](#)" - at the San Antonio Breast Cancer Symposium (SABCS) and ONS Congress, respectively. The program is designed to provide a voice to cancer survivors who are no longer willing to accept debilitating side effects of cancer treatments as an acceptable trade-off for survival. Visit the [Make Cancer Less Shitty](#) program at [makecancerlessshitty.com](#) and on [X](#), [Facebook](#) & [Instagram](#).
- In January 2024, a study published in the peer-reviewed journal [PLOS ONE](#) showed statistically significant results for use of crofelemer for preventive treatment of CTD in dogs. On December 21, 2021, the [U.S. Food and Drug Administration](#) conditionally approved Canalevia[®]-CA1 (crofelemer delayed-release tablets) for the treatment of chemotherapy-induced diarrhea (CID) in dogs.

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. The OnTarget study is testing whether crofelemer (versus placebo) can prevent (or substantially reduce) diarrhea when any one of the selected 23 targeted therapies (that are associated with diarrhea in at least 50% of patients) is initiated.



Image of *Croton lechleri* tree, the source of crofelemer

About Cancer Therapy-Related Diarrhea (CTD)

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 More than 2 million people are expected to be diagnosed with cancer in 2024 in the U.S., according to the American Cancer Society.² Cancer patients with diarrhea have been shown to be 40% more likely to discontinue their targeted therapy.³

About Oral Mucositis

Oral mucositis is a common, painful, and debilitating cancer treatment-related side effect.⁴ Up to 40% of all patients treated with chemotherapy develop oral mucositis, and this percentage rises to approximately 90% for patients with head and neck cancers treated with chemotherapy and radiotherapy.⁵ Of the latter, 19% may end up being hospitalized, which may negatively impact quality of life and increase healthcare utilization costs.⁵

Oral mucositis can cause an inability to eat or talk, and an increased risk of infection. It may also result in treatment delays or dose reductions to manage symptoms.⁴

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. Crofelemer also is the subject of Napo's phase 3 OnTarget clinical trial for preventive treatment of cancer therapy-related diarrhea (CTD). 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 at makecancerlessshitty.com and on [X](#), [Facebook](#) & [Instagram](#)

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that Jaguar will provide the results of the OnTarget trial and updates on the company's cancer supportive care portfolio on or before July 23, 2024, and the expectation that Jaguar will hold an investor webcast on or before July 23, 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 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 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

² American Cancer Society. Cancer Facts & Figures 2024. Available: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2024/2024-cancer-facts-and-figures-acf.pdf> Accessed June 10, 2024.

³ Okhuysen PC, Schwartzberg LS, Roeland E, et al. The impact of cancer-related diarrhea on changes in cancer therapy patterns. *J Clin Oncol.* 2021; 39:15_suppl, 12111-12111.

⁴ The Oral Cancer Foundation. Mucositis. Accessed March 26, 2024. Available at <https://oralcancerfoundation.org/complications/mucositis/>

⁵ Pulito C, Cristaudo A, Porta CL, et al. Oral mucositis: the hidden side of cancer therapy. *J Exp Clin Cancer Res.* 39, 210 (2020). <https://doi.org/10.1186/s13046-020-01715-7>

Contact:

hello@jaguar.health

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