



## Jaguar Announces Over-Enrollment in its Pivotal Phase 3 OnTarget Trial of Crofelemer for Prophylaxis of Cancer Therapy-Related Diarrhea

May 25, 2023

**256-patient enrollment target met plus 11% over-enrollment; Primary endpoint based on patient reported outcomes from study expected in October 2023**

**SAN FRANCISCO, CA / ACCESSWIRE / May 25, 2023 / [Jaguar Health, Inc.](#)** (Nasdaq:JAGX) ("Jaguar" or the "Company") today announced that the Company has successfully over-enrolled its global, pivotal, Phase 3 [OnTarget](#) clinical trial of crofelemer for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy with or without chemotherapy.

"As anticipated, we over-enrolled our ongoing placebo-controlled OnTarget trial by 11% after completion of the targeted enrollment of 256 patients," said Pravin Chaturvedi, PhD, Jaguar's Chair of the Scientific Advisory Board and Chief Scientific Officer, "and we look forward to the expected availability of top line results from this study in October 2023."

"As we closed down enrollment, over-enrollment occurred as we permitted participating clinics to enroll additional eligible patients who were in the screening pipelines at some of the sites," said Lisa Conte, Jaguar's president and CEO. "We're very happy to make this announcement shortly after [Clinical Trials Day](#), which occurs on May 20<sup>th</sup> each year. The full potential of clinical research to change lives can only be unlocked when patients, clinical researchers, regulatory agencies, and industry work together, embrace each other's perspectives, and invest in shared goals. We are grateful both to the hundreds of cancer patients who participated in the OnTarget study and to all the sites and investigators in the U.S., Serbia, Georgia, Argentina, and Taiwan who helped us accomplish this important enrollment milestone."

The OnTarget study is a first-of-its-kind prophylactic clinical trial with a primary endpoint based on patient reported outcomes that address the highly neglected and unmet burden of cancer therapy-related diarrhea. This study will evaluate the benefit of crofelemer to prevent or substantially reduce the number of weekly loose/watery stools as a continuous measurement over the 12-week treatment period compared to placebo. By completing the targeted enrollment, the OnTarget study has approximately 90% power to detect the difference in the incidence and severity of diarrhea between crofelemer and placebo.

The Company's expectation is that the double-blind placebo controlled OnTarget trial will provide evidence that diarrhea associated with targeted cancer therapies is chronic, not acute, and impacts the patient's ability to perform activities of daily living as well as remain on their cancer therapy regimens at proven doses for better outcomes. The OnTarget trial is evaluating the effectiveness of crofelemer's novel mechanism of action - the modulation of two gastrointestinal chloride ion channels - to mitigate or substantially reduce chronic cancer therapy-related diarrhea.

### **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,<sup>1</sup> and the cost of care of CTD patients is estimated to be 2.9 times higher than for patients who are not experiencing CTD.<sup>2</sup>

### **About Jaguar Health, Napo Pharmaceuticals, Napo Therapeutics, & Jaguar Animal Health,**

Jaguar Health, Inc. 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 candidate 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 the development of rare disease indications of crofelemer and 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 Pharmaceuticals, visit [www.napopharma.com](http://www.napopharma.com). For more information about Napo Therapeutics, visit [napotherapeutics.com](http://napotherapeutics.com).

## Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that top line results from the OnTarget trial will be available in October 2023, and the expectation that the OnTarget trial will provide evidence that diarrhea associated with targeted cancer therapies is chronic, not acute, and impacts the patient's ability to perform activities of daily living as well as remain on their cancer therapy regimens at proven doses for better outcomes. 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.

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

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

### CONTACT:

[hello@jaguar.health](mailto:hello@jaguar.health)

Jaguar-JAGX

**SOURCE:** Jaguar Health, Inc.

[accesswire.com](https://www.accesswire.com)

<https://www.accesswire.com/757139/Jaguar-Announces-Over-Enrollment-in-its-Pivotal-Phase-3-OnTarget-Trial-of-Crofelemer-for-Prophylaxis-of-Cancer-Therapy-Related-Diarrhea>