



Jaguar Health Achieves Approximately 75% Enrollment in Pivotal Phase 3 OnTarget Trial of Crofelemer for Cancer Therapy-Related Diarrhea

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Addition of [OnTarget](#) trial sites in Europe, South America and Asia has significantly accelerated enrollment, which is expected to complete in Q2 2023

Adoption of premier digital health technology for data collection facilitates operational efficiency of this global trial

SAN FRANCISCO, CA / ACCESSWIRE / February 21, 2023 / [Jaguar Health, Inc.](#) (Nasdaq:JAGX) ("Jaguar" or the "Company") today announced that patient enrollment has reached approximately 75% in the Company's pivotal Phase 3 [OnTarget](#) clinical trial of crofelemer for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy, with or without chemotherapy. Target trial enrollment of 256 patients is expected to complete in the second quarter of 2023.

Crofelemer, the Company's oral botanical drug, is an anti-secretory antidiarrheal agent that modulates gastrointestinal (GI) chloride ion channels to ameliorate diarrhea. It is marketed as Mytesi[®] and received approval from the U.S. Food and Drug Administration (FDA) for its initial indication of the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.

"We are very excited that enrollment in OnTarget has reached approximately 75%. Our efforts over the past year to expand the trial to new U.S. and international sites - with trial sites now active in Georgia, the Republic of Serbia, Argentina, and Taiwan - has significantly accelerated enrollment," said Darlene Horton, MD, the Company's Chief Medical Officer. "Additionally, I am pleased to report that our original decision to leverage premier digital health technology for data collection in OnTarget greatly facilitates the operational efficiency of a global trial. Our expectation is that the 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 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 chloride ion channels in the gastrointestinal tract - to mitigate or substantially reduce chronic cancer therapy-related diarrhea."

About Cancer Therapy-Related Diarrhea

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.

About Mytesi[®]

Mytesi (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

See full Prescribing Information at [Mytesi.com](#). Crofelemer, the active ingredient in Mytesi, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

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, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human pharmaceuticals from plants harvested responsibly from rainforest areas. 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 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. For more information about Napo Therapeutics, visit napotherapeutics.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that enrollment in the OnTarget trial will complete in the second quarter of 2023, and the Company's 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 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.

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