



Napo Pharmaceuticals, a Jaguar Health Family Company, Accepted to Present Results of Its Pivotal Phase 3 OnTarget Study for Preventive Treatment of Cancer Therapy-Related Diarrhea December 7th at the San Antonio Breast Cancer Symposium

October 25, 2023

Top line results of this pivotal trial expected before Thanksgiving

More than 1 million cancer patients in the US receive chemotherapy or radiation each year, according to the CDC, and cancer patients with diarrhea are 40% more likely to discontinue their targeted therapy

SAN FRANCISCO, CA / ACCESSWIRE / October 25, 2023 / [Napo Pharmaceuticals](#) (Napo), a [Jaguar Health, Inc.](#) (NASDAQ:JAGX) family company, today announced that on December 7, 2023, the company will present results from its pivotal Phase 3 [OnTarget](#) study of Napo's plant-based prescription drug crofelemer under investigation for the prophylaxis (prevention) of diarrhea associated with targeted cancer therapies used to treat solid tumors at the [San Antonio Breast Cancer Symposium](#) (SABCS). Napo expects to announce top line results of the trial by the Thanksgiving holiday.

Since 1977, SABCS has been the leading scientific conference for scientists, physicians, clinical investigators, breast care providers, and advocates seeking an exchange of new information in experimental biology, etiology, prevention, diagnosis, and therapy of premalignant breast disease and breast cancer.

"We are very happy to have been accepted to present the important results of the OnTarget trial at SABCS this December," said Lisa Conte, Jaguar's president and CEO. "Diarrhea is a common occurrence with targeted therapies such as tyrosine kinase inhibitors, EGFR, HER2 and PARP inhibitors, and immunotherapy, and can also occur with chemotherapy. More than 80 oral targeted cancer therapies are FDA approved, many of which cause diarrhea in 50-100% of patients."

More than 1 million cancer patients in the US receive chemotherapy or radiation each year,¹ according to the Centers for Disease Control and Prevention (CDC). Cancer patients with diarrhea have been shown to be 40% more likely to discontinue their targeted therapy.² The OnTarget study is testing whether crofelemer (versus placebo) can prevent (or substantially reduce) diarrhea when any one of 24 different targeted therapies (that are associated with diarrhea in at least 50% of patients) is started.

About the Phase 3 OnTarget Clinical Trial

The multicenter double-blind, placebo-controlled OnTarget study is a first-of-its-kind prophylactic clinical trial with a primary endpoint based on patient-reported outcomes that address the high unmet burden of cancer therapy-related diarrhea (CTD). Debilitating diarrhea (loose and/or watery stools), fecal incontinence, and urgency can be extremely limiting to patients' daily living activities. Napo also refers to this multi-symptom condition as chemotherapy-induced overactive bowel (CIOB).

The OnTarget study is evaluating the benefit of crofelemer's novel mechanism of action, intestinal chloride ion channel modulation, to prevent or substantially reduce CTD and other symptoms of CIOB as a continuous measurement over the 12-week treatment period compared to placebo.

About Chemotherapy-Induced Overactive Bowel (CIOB)

A significant proportion of patients undergoing cancer therapy experience chemotherapy-induced overactive bowel (CIOB) - which includes symptoms such as chronic debilitating diarrhea (loose and/or watery stools), urgency, and bowel incontinence. Diarrhea has the potential to cause dehydration, and worsen fatigue 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 and/or 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 worsening patient outcomes. Diarrhea is also a common side effect of some approved CDK 4/6 inhibitors. Patients with cancer therapy-related diarrhea (CTD) are 40% more likely to discontinue their chemotherapy or targeted therapy than patients without CTD,² and the cost of care of CTD patients is estimated to be 2.9 times higher than for patients who are not experiencing CTD.³

About Crofelemer

Crofelemer is the only oral FDA-approved prescription drug under botanical guidance. It is plant-based, extracted and purified from the red bark sap of the *Croton lechleri* tree in the Amazon Rainforest. Napo Pharmaceuticals, a Jaguar family company, 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, an ongoing 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/>

Visit Jaguar on X: https://twitter.com/Jaguar_Health

Visit Jaguar on Instagram: <https://www.instagram.com/jaguarhealthcommunity/>

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that top line results of the OnTarget trial will be available by the 2023 Thanksgiving holiday, and the expectation that results from the OnTarget study will be presented December 7, 2023 at SABCS. 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 <https://www.cdc.gov/cancer/preventinfections/providers.htm#print>

² Pablo C. Okhuysen, M.D., The impact of cancer-related diarrhea on changes in cancer therapy patterns: Real world evidence

³ Eric Roeland, M.D., FAAHPM, Healthcare utilization and costs associated with cancer-related diarrhea

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SOURCE: Jaguar Health, Inc.