

Jaquar Health to Present December 5 at the MedInvest Oncology Investor Conference

November 30, 2023

Top line data for Jaguar Health's pivotal phase 3 <u>OnTarget</u> trial of crofelemer for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy forthcoming

SAN FRANCISCO, CA / ACCESSWIRE / November 30, 2023 / Jaguar Health, Inc. (NASDAQ: JAGX) today announced that Lisa Conte, the company's founder, president and CEO, will present virtually on December 5, 2023 at the MedInvest Oncology Investor Conference.

Participation Instructions for Jaguar Health's Virtual Presentation at the MedInvest Oncology Investor Conference

When: Tuesday, December 5, 2023 from 9:55 AM - 10:10 AM Pacific Standard Time

Registration link for presentation: Click Here

About the Phase 3 OnTarget Clinical Trial

The OnTarget trial is evaluating the company's plant-based prescription drug crofelemer for prophylaxis (prevention) of diarrhea in adult cancer patients with solid tumors receiving targeted therapy, with or without standard chemotherapy - an indication Napo also refers to as preventive treatment of chemotherapy-induced overactive bowel (CIOB) - which includes symptoms such as chronic debilitating diarrhea (loose and/or watery stools), urgency, and bowel incontinence. The 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 CIOB, including specifically diarrhea/loose watery stools. This study is evaluating the benefit of crofelemer to prevent or substantially reduce the number of weekly loose and/or watery stools as a continuous measurement over the 12-week treatment period compared to placebo. By completing the targeted enrollment in stage 1, 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 CIOB associated with targeted cancer therapies is chronic, not acute, and impacts the patient's quality of life as well as their 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, intestinal chloride ion channel modulation, to mitigate or substantially reduce chronic cancer therapy-related diarrhea and other symptoms of CIOB.

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 impacting patient outcome. Diarrhea is also a common side effect of some approved CDK 4/6 inhibitors. Patients with cancer-related diarrhea (CTD) are 40% more likely to discontinue their chemotherapy or targeted therapy than patients without CTD, 1 and the cost of care of CTD patients is estimated to be 2.9 times higher than for patients who are not experiencing CTD.2

Rare Disease Business Opportunity

Jaguar is supporting investigator-initiated and investigator IND proof-of-concept studies of crofelemer for microvillus inclusion disease (MVID) and short bowel syndrome (SBS) with intestinal failure in the US, EU and Middle East/North Africa (MENA) regions, with results expected before the end of 2023 and in 2024. In accordance with the guidelines of specific European Union countries, published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID, potentially in 2024, for these debilitating conditions.

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 Jaquar 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://iaguar.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 Jaguar Health management will present December 5, 2023 at the MedInvest Oncology Investor Conference, Jaguar Health's expectation that top line results from the OnTarget study are forthcoming, 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 quality of life as well as their ability to remain on their cancer therapy regimens at proven doses for better outcomes, and the expectation that results of proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure will be available before the end of 2023 and in 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.

CONTACT:

hello@jaguar.health Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

accesswire.com

https://www.accesswire.com/811610/jaguar-health-to-present-december-5-at-the-medinvest-oncology-investor-conference

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

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