

# Jaguar Health to Present October 3 at LD Micro's Main Event Investor Conference, and on October 5 at the Global Capital Network Investor Conference

### September 28, 2023

Top line results expected late October 2023 for company's phase 3 OnTarget trial of crofelemer for preventative treatment of cancer therapy-related diarrhea

Jaguar is supporting investigator-initiated proof-of-concept studies of crofelemer for the rare disease indications of short bowel syndrome and microvillus inclusion disease in the US, EU, and Middle East/North Africa regions, with results expected before the end of 2023 and in 2024

SAN FRANCISCO, CA / ACCESSWIRE / September 28, 2023 / Jaguar Health, Inc. (NASDAQ: JAGX) today announced that company management will present at the LD Micro Main Event investor conference on October 3, 2023, and at the Global Capital Network Investor Conference on October 5, 2023.

### Participation Instructions for Jaguar Presentation at LD Micro Main Event

When: Tuesday, October 3, 2023 from 12:00-12:25 PM Pacific Daylight Time in Track 3

Where: Luxe Sunset Boulevard Hotel, 11461 Sunset Blvd, Los Angeles, CA 90049

Registration link for conference: Click Here

#### Participation Instructions for Jaguar Presentation at Global Capital Network Investor Conference

When: Thursday, October 5, 2023 during the MedTech segment of the conference

Where: Newport Beach Hyatt, 1107 Jamboree, Newport Beach, CA 92660

Registration link for conference: Click Here

As recently announced by Napo Pharmaceuticals (Napo), a Jaguar family company, the last patient has completed their final visit for the stage 1 primary endpoint treatment period of Napo's pivotal Phase 3 <u>OnTarget</u> trial of crofelemer for preventive treatment of diarrhea in adult cancer patients with solid tumors receiving targeted therapy with or without standard chemotherapy. This trial is studying 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. Top-line results for the primary endpoint in this trial are expected the last week of October 2023.

# About the Phase 3 OnTarget Clinical Trial

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 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 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>

# **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. 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.

# 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 <u>OnTarget</u> 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., is focused on developing novel prescription medicines derived from plants for mental health indications.

For more information about Jaguar Health, please visit <u>https://jaguar.health</u>. For more information about Napo Pharmaceuticals, visit <u>www.napopharma.com</u>. For more information about Napo Therapeutics, visit <u>napotherapeutics.com</u>. For more information about Magdalena Biosciences, visit <u>magdalenabiosciences.com</u>.

# **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that company management will present on October 3, 2023 at LD Micro's Main Event investor conference, and on October 5, 2023 at the Global Capital Network Investor Conference, the company's expectation that top line results from the OnTarget study will be available in late October 2023, 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.

<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

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