



Jaguar Completes Enrollment in Its Pivotal Phase 3 OnTarget Trial of Crofelemer for Prophylaxis of Cancer Therapy-Related Diarrhea

May 9, 2023

Primary endpoint based on patient reported outcomes from study expected in October 2023

With the completion of the PIPE financing of unregistered shares and 6-month lock up term, Jaguar has agreed, as described below, not to issue additional equity securities before October 22, 2023 - by which point the Company expects to have released top line data for the [OnTarget](#) trial

SAN FRANCISCO, CA / ACCESSWIRE / May 9, 2023 / [Jaguar Health, Inc.](#) (NASDAQ:JAGX) ("Jaguar" or the "Company") today announced that it has completed enrolling the target number of 256 patients in the Company's global, pivotal, Phase 3 [OnTarget](#) clinical trial of crofelemer for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy with or without chemotherapy.

"The Company's current cash position includes anticipated gross proceeds from a PIPE (private investment in public equity) transaction of approximately \$1.86 million involving the issuance and sale of approximately 3,425,000 shares of unregistered Jaguar Common Stock and 6,850,000 warrants not exercisable until the later of January 1, 2024 and stockholder approval, that is expected to close on May 9, 2023, subject to customary closing conditions," said Lisa Conte, Jaguar's president and CEO. "This financing involves a small group comprised primarily of dedicated, long-term Jaguar investors. Pursuant to the terms of the PIPE purchase agreement ("the Agreement"), each participating investor agreed not to sell or transfer any Jaguar equity securities for a period commencing on the signing of the Agreement and ending six months after the PIPE closing. There are no anti-dilution, reset, or variable pricing rights associated with the securities issued in the PIPE. We believe this financing illustrates the confidence that the participating investors have in the Company and the expectation that both the OnTarget trial and our focus on development of proof-of-concept data for crofelemer for the rare disease indications of short bowel syndrome (SBS) with intestinal failure and congenital diarrheal disorders (CDD) will prove transformational in 2023 for Jaguar value recognition."

The exercise of the warrants included in the PIPE is subject to shareholder approval.

The Agreement also provides that during the period commencing on the signing of the Agreement and ending on October 22, 2023 (a time period that extends to the expected release date of the primary endpoint for the OnTarget trial), the Company will not effect or enter into any agreement to (i) issue securities in exchange for any securities of the Company issued and outstanding on the date of the Agreement pursuant to Section 3(a)(9) of the Securities Act of 1933, as amended (the "Securities Act"), including ATM utilization or (ii) effect issuance by the Company of common stock or common stock equivalents, subject to certain customary carve outs set forth in the Agreement or with the consent of holders of a majority of shares issued in the PIPE. For a summary of the terms and conditions of the PIPE and copies of the key documents, please see the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 9, 2023.

The Company plans to use the proceeds from the PIPE transaction to fund Company operations and support the ongoing operation of the OnTarget trial.

"We are very pleased to have reached our target enrollment figure of 256 patients in the OnTarget trial, Jaguar's flagship development program for the prophylaxis of cancer therapy-related diarrhea," said Darlene Horton, MD, the Company's Chief Medical Officer. "This is a major milestone in the history of the Company and a key step on our journey to making crofelemer available to treat the critical unmet need of chronic cancer therapy-related diarrhea. Our entire team is deeply grateful to the study participants and to their families, as well as to the study investigators and clinical staff, for working so diligently to help us meet this significant milestone. As we close down enrollment, we are permitting participating clinics to enroll additional cancer patients who are in their screening pipelines. The top line results from this pivotal study are expected early in the fourth quarter of 2023."

"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," said Pravin Chaturvedi, PhD, Jaguar's Chair of the Scientific Advisory Board and Chief Scientific Officer. "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 our targeted enrollment, the OnTarget study has approximately 90% power to detect the difference in the incidence and severity of diarrhea between crofelemer and placebo."

"Supportive care is cancer care, and our Company takes great pride in incorporating the patient voice in developing solutions to address the comfort and dignity of the patient as they manage their cancer treatment journey and their ability to adhere to their targeted cancer therapy," Conte said.

The Company's 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 gastrointestinal chloride ion channels - to mitigate or substantially reduce chronic cancer therapy-related diarrhea.

The securities to be issued in the PIPE described above have not been registered under the Securities Act of 1933, as amended. Accordingly, these securities may not be offered or sold in the United States, except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act. The Company has agreed to file a registration statement with the Securities and Exchange Commission registering the resale of the shares of common stock issuable upon conversion of the preferred stock and exercise of warrants issued in this PIPE no later than two weeks after public release of the results of the primary endpoint of the pivotal OnTarget trial.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction.

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,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

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. 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 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 the Company's expectation that top line data for the OnTarget trial will be released by October 22, 2023, the Company's expectation that the PIPE transaction will close on May 9, 2023, the Company's expectation that both the OnTarget trial and the Company's focus on development of proof-of-concept data for crofelemer for the indications of SBS with intestinal failure and CDD will prove transformational in 2023 for Jaguar value recognition, 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.

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

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