Jaguar Health Announces Submission of Investigational New Drug (IND) Application to FDA for Drug Candidate for the Symptomatic Relief of Diarrhea from Cholera

August 30, 2022

Jaguar is concentrating financial and management resources on two near-term late-stage clinical events

SAN FRANCISCO, CA / ACCESSWIRE / August 30, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") today announced the submission by the Company's wholly owned subsidiary, Napo Pharmaceuticals (Napo), of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration for Napo's NP-300 drug product candidate for the symptomatic relief of diarrhea from cholera.

"I am very pleased that we have submitted the IND to FDA for the proposed cholera-related diarrhea indication for NP-300," said Steven King, PhD, Jaguar's Chief Sustainable Supply, Ethnobotanical Research & IP Officer. "NP-300 and crofelemer have a similar physiological anti-secretory mechanism of action to reduce chloride ion secretion into the gut lumen and improve stool consistency. The Company has previously presented Phase 2 data on crofelemer for the treatment of devastating dehydration in cholera patients from the renowned International Centre for Diarrhoeal Disease Research (icddr,b) in Bangladesh."

Upon approval of NP-300 for the symptomatic relief of diarrhea from cholera, the Company intends to pursue a Tropical Disease Priority Review Voucher ("TDPRV") under the FDA's financial incentive program to develop NP-300 for this indication. Priority review vouchers are transferable, and in past transactions by other companies have sold for values ranging from $67 million to $350 million, which provides for a potential immediate return on investment upon approval of NP-300 for the cholera-related diarrhea indication.

As part of a $6.0 million financing **agreement** with Streeterville Capital, LLC (Streeterville) in 2021, providing Streeterville the right to 18% of the gross proceeds from the sale of a possible TDPRV, Jaguar was previously subject to a requirement to initiate a Phase 1 clinical trial of NP-300 for the cholera-related diarrhea indication by September 30, 2022.

"With this IND filed, the Company is well positioned to initiate the clinical program for the cholera-related diarrhea indication when our development team has the resources and bandwidth to make this indication a core focus. In this difficult market for early-stage drug development funding, Jaguar is focusing resources and effort on the near-term late-stage clinical events in the next approximately 6 to 12 months that we expect to be transformational in terms of value creation and recognition for the Company," said Lisa Conte, Jaguar's president and CEO. "We anticipate the completion in 2022 of an investigator-initiated proof-of-concept study of crofelemer for short bowel syndrome (SBS), supporting the potential for expanded patient access to crofelemer in Europe in 2023 for this devastating and catastrophic disease. The investigator is targeting the presentation in December 2022 of results from the SBS study at a global GI conference in Dubai. Our second key clinical activity is our Phase 3 pivotal OnTarget trial of crofelemer for our core follow-on indication of prophylaxis of cancer therapy-related diarrhea (CTD). We expect enrollment in this trial to complete in the first half of 2023."

In support of the IND application filing for NP-300 for the symptomatic treatment and relief from infectious diarrhea from pathogens such as *Vibrio cholerae*, the Company received partial financial support for certain IND enabling preclinical toxicity studies by the National Institute of Allergy and Infectious Diseases (NIAID). NIAID is part of the National Institutes of Health.

Cholera is an acute diarrheal illness caused by infection of the intestine with the bacterium *Vibrio cholerae*. Although cholera is an orphan indication in the United States, it is estimated that, worldwide, 1.3 to 4 million cholera cases and 21,000 to 143,000 cholera-related deaths occur each year, according to the Centers for Disease Control and Prevention of the U.S. Department of Health & Human Services. Approximately one in 10 of infected persons will have severe disease characterized by profuse watery diarrhea, vomiting, and leg cramps. In these people, rapid loss of body fluids leads to dehydration and shock. Without treatment, death can occur within hours. Cholera is now endemic in many countries outside the United States. The largest cholera outbreak in recorded history occurred recently in Yemen. According to Oxfam, the number of cholera cases in Yemen in 2019 was the second largest ever recorded in a country in a single year, surpassed only by the numbers in Yemen in 2017.

NP-300, a novel oral botanical drug product that is sustainably derived from the same source as crofelemer - the *Croton lechleri* tree - is planned to be developed under FDA Botanical Guidance. As stated on the FDA's website, crofelemer is currently one of only two botanical products that have been approved under the FDA's Botanical Guidance definition of a botanical drug product.

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.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's expectation that two near-term late-stage clinical events in the next approximately 6 to 12 months will be transformational in terms of value creation and recognition for the Company, Jaguar's expectation that enrollment in the OnTarget trial will complete in the first half of 2023, Jaguar's expectation an investigator-initiated proof-of-concept study of crofelemer for SBS will be completed in 2022, the Company's expectation that the results of this SBS study will support the potential for reimbursed expanded patient access through programs in Europe in 2023 for SBS, Jaguar's expectation that the investigator for the SBS study will present the study results in December 2022 at a global GI conference in Dubai, and the Company's expectation that it will pursue a TDPRV related to the proposed cholera-related diarrhea indication for NP-300. 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.

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