Jaguar Health Subsidiary Napo Pharmaceuticals Announces Activation by FDA of Investigational New Drug (IND) Application for NP-300, a Novel Drug Candidate for the Symptomatic Relief and Treatment of Diarrhea from Cholera and Other Pathogens

September 29, 2022

SAN FRANCISCO, CA / ACCESSWIRE / September 29, 2022 / Napo Pharmaceuticals, Inc. ("Napo"), the wholly-owned subsidiary of Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") today announced the activation by the U.S. Food and Drug Administration (FDA) of the Investigational New Drug (IND) application for Napo's NP-300, a novel drug product candidate for the symptomatic relief and treatment of moderate-to-severe diarrhea, with or without concomitant antimicrobial therapy, from bacterial, viral and parasitic infections including *Vibrio cholerae*, the bacterium that causes cholera.

"We were very pleased to hear from the FDA that they have completed their review of our IND application for NP-300 and concluded that Napo may proceed with its proposed phase I clinical trial for the drug. Following the completion of the phase I trial, the Company will be positioned to initiate the next stage of our clinical development program for cholera-related diarrhea when our development team has the requisite resources and bandwidth to initiate the additional required trials," said Lisa Conte, Jaguar's president and CEO. "We are grateful for the partial financial support from the National Institute of Allergy and Infectious Diseases (NIAID) to support the NP-300 preclinical program."

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

Upon completion of the requisite development activities to support the New Drug Application (NDA) and subsequent approval of NP-300 by the FDA for the symptomatic relief and treatment 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.

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 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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