



Napo Pharmaceuticals, a Jaguar Health Family Company, Submits Funding Application to National Institute of Allergy and Infectious Diseases for Development of NP-300 Drug Candidate for Cholera-Related Diarrhea

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Cholera is an acute diarrheal illness caused by infection of the intestine with the bacterium *Vibrio cholerae*

Jaguar intends to pursue a Tropical Disease Priority Review Voucher, under FDA's financial incentive program, to develop NP-300 for this indication

SAN FRANCISCO, CA / ACCESSWIRE / September 12, 2023 / [Napo Pharmaceuticals](#) (Napo), a [Jaguar Health](#) (NASDAQ:JAGX) (Jaguar) family company, today announced that it has submitted a grant application to the National Institute of Allergy and Infectious Diseases (NIAID) for funding to support Napo's Phase I study of NP-300, the company's 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.

"I am very pleased that this grant application has been filed," said Michael K. Guy, DVM, PhD, Napo's Vice President of Preclinical and Nonclinical Studies. "We look forward to the day when NP-300 may be available to provide symptomatic relief and treatment of dehydrating diarrhea from acute infections such as that with cholera."

As [announced](#), Napo's Investigational New Drug (IND) application for NP-300 was activated by the U.S. Food and Drug Administration (FDA) in September 2022. In support of the IND application filing, the company received partial financial support for certain IND-enabling preclinical toxicity studies from NIAID. NIAID is part of the National Institutes of Health.

Although cholera is an orphan indication in the US, 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 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 U.S. 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 drug product that is sustainably derived from the *Croton lechleri* tree, the same source as that for Napo's crofelemer drug product, 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, 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 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 [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, please visit <https://jaguar.health>. For more information about Napo Pharmaceuticals, visit www.napopharma.com. For more information about Napo Therapeutics, visit napotherapeutics.com. For more information about Magdalena

Biosciences, visit magdalenabiosciences.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that NP-300 will be developed under the FDA's Botanical Guidance, and Jaguar's expectation that the company will pursue a Tropical Disease Priority Review Voucher 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 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.

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