



## Jaguar Health Announces Appointment of Pravin Chaturvedi, Ph.D., as Chief Scientific Officer

April 5, 2022

*Dr. Chaturvedi continues to serve as Chair of company's Scientific Advisory Board*

*Dr. Chaturvedi continues to provide leadership to the development of two crofelemer pipeline indications, with anticipated key milestones in the next 12-15 months.*

**SAN FRANCISCO, CA / ACCESSWIRE / April 5, 2022** / Jaguar Health, Inc. (**NASDAQ:JAGX**) (Jaguar) today announced that Pravin Chaturvedi, PhD, a pharmaceutical veteran and leading clinical development expert, has been appointed Chief Scientific Officer (CSO) and Chair of the Scientific Advisory Board (SAB) of Jaguar. Prior to this appointment, Dr. Chaturvedi served as Chair of the company's SAB and Acting CSO of Jaguar and Napo Pharmaceuticals (Napo), Jaguar's wholly owned subsidiary.

"We are absolutely thrilled that Pravin is now a full-time Jaguar executive officer in the role of CSO. Jaguar is focused on two important crofelemer pipeline development activities in the next 12-15 months that are expected to be value-transforming and require Pravin's full time commitment and leadership: the completion of the Phase 3 pivotal [OnTarget](#) trial of our core follow-on indication for crofelemer's novel mechanism of action, prophylaxis of cancer therapy-related diarrhea (CTD); and heading up development collaborations for the important rare disease indications of short bowel syndrome (SBS) and congenital diarrheal disorders (CDD) under the exclusive license granted to Napo Therapeutics, the Italian corporation established by Jaguar in 2021 and led by an impressive team of professionals with rare disease management experience. We also expect investigator-initiated proof-of-concept studies of crofelemer for SBS and CDD to be completed in 2022 and 2023, supporting the potential for expanded patient access through programs in Europe for these devastating and catastrophic diseases and health situations for these patients, who are often on parenteral nutrition for as long as 20 hours a day, seven days a week."

During his impressive career, Dr. Chaturvedi has developed and brought to market seven pharmaceutical products in the U.S., and his list of accomplishments includes designing the successful Phase 3 ADVENT trial of crofelemer that resulted in approval of the drug in the U.S., now marketed under the name Mytesi<sup>®</sup>, for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.

"Given the expanded opportunities for crofelemer therapeutic applications, I am delighted to be a part of the Jaguar team and a key collaborator with Napo Therapeutics. We applied important lessons from Mytesi's successful pivotal ADVENT trial when designing the protocol and endpoints for our OnTarget Phase 3 study of crofelemer for CTD, in addition to discussing the OnTarget trial design with FDA before initiating the trial in October 2020," said Dr. Chaturvedi. "We plan to complete enrollment of the CTD study in the first half of 2023."

Further details about the trial can be viewed [here](#) on the [clinicaltrials.gov](#) website. Adult patients with solid tumors receiving targeted therapy with or without chemotherapy experience CTD, which is a common side effect of cancer therapy. A recent report indicated that these patients are 40% more likely to reduce or discontinue their chemotherapy or targeted therapy than patients without CTD.<sup>1</sup>

As part of his responsibilities as CSO and Chair of the SAB, Dr. Chaturvedi will also support Napo Therapeutics' efforts to initiate a pivotal clinical trial of crofelemer for SBS. In the fourth quarter of 2021, the European Medicines Agency (EMA) granted orphan-drug designation (ODD) for crofelemer for SBS following submission of Napo Therapeutics' ODD application, which included epidemiological data for the incidence and prevalence of SBS, data on the pathophysiology of SBS, support for the mechanistic rationale for crofelemer for SBS, medical plausibility information for crofelemer for SBS, together with preclinical pharmacology and patient case studies. Crofelemer received ODD in the U.S. for SBS in 2017; and an additional patient case study has been submitted for publication. Napo Therapeutics' novel formulation of crofelemer is expected to be more appropriate for SBS patients and would allow for more dosing flexibility for SBS patients. Napo Therapeutics was established in Europe in part because of the EMA's commitment to enabling early patient access to new medicines, particularly those that target an unmet medical need, and ODD status in the EU is expected to support Napo Therapeutics' plans to make crofelemer available through Early Access Programs in the EU for SBS. Participation in Early Access Programs provides a potential opportunity for revenue generation in addition to the ability to impact important morbidity, mortality, and the cost of care for chronically ill patients for whom no therapeutic options exist. Current treatment options include GLP-2 analogs, and the global SBS market exceeded \$568 million in 2019 according to a report by Vision Research Reports. Despite limitations in target patients and associated toxicity, and the recognition of the unmet medical need represented by the granting of ODD to crofelemer for SBS, the global GLP-2 analog market is expected to reach \$4.6 billion by 2027, according to the report from Vision Research Reports.

An analyst report by CWIC Equity Solutions in the UK regarding the Napo Therapeutics opportunity can be found [here](#) on the investor relations section of Jaguar's website.

Over his 30+ year career in the pharmaceutical industry, Dr. Chaturvedi has participated in the successful development and commercialization of multiple drugs in the therapeutic areas of epilepsy, HIV, hepatitis C, memory, and gastrointestinal disorders in addition to co-founding and leading

multiple biotech enterprises. He served as the President and Chief Scientific Officer of Napo from 2006 to 2013 and remained a scientific adviser of Napo from 2013 through 2017. From 2001 through 2004, he served as the President, Chief Executive Officer and Director of Scion Pharmaceuticals, Inc. He is the founder of IndUS Pharmaceuticals, where he has served as Chairman and Director since 2017, and held the same roles from 2005 through 2007 and from 2010 through 2015. IndUS Pharmaceuticals merged with Pivot Pharmaceuticals in 2015 and Dr. Chaturvedi served as the President and CEO of Pivot Pharmaceuticals from 2015 to 2017, prior to assuming his role as the Chair of the SAB for Napo and Jaguar. Dr. Chaturvedi also co-founded Oceanyx Pharmaceuticals, where he has served as Chief Executive Officer and Director since 2011, and he continues to serve on the boards of IndUS, Oceanyx, Enlivity and Cellanyx. He has been an adjunct faculty member at Georgetown University since 2013. Earlier in his career, from 1994 through 2001, Dr. Chaturvedi served in various roles as the head of lead evaluation at Vertex Pharmaceuticals, and from 1993 through 1994 he was in the preclinical group at Alkermes Inc. He started his career in the product development group at Parke-Davis/Warner-Lambert Company (now Pfizer) in 1988, where he worked through 1993. Dr. Chaturvedi holds a Ph.D. in Pharmaceutical Sciences from West Virginia University and a Bachelor's in Pharmacy from the University of Bombay.

Mytesi (crofelemer) is a non-opiate, plant-based, chloride ion channel modulating antidiarrheal medicine. The only oral plant-based prescription medicine approved under FDA Botanical Guidance, Mytesi has a novel mechanism of action that works locally in the gut by gently and effectively modulating and normalizing the flow of water and electrolytes with minimal systemic absorption.

#### **About Jaguar Health, Jaguar Animal Health, Napo Pharmaceuticals, & Napo Therapeutics**

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 Animal Health is a tradename of Jaguar Health. 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.

For more information about Jaguar Health, please visit <https://jaguar.health>. For more information about Napo Pharmaceuticals, visit [www.napopharma.com](http://www.napopharma.com). For more information about Napo Therapeutics, visit [www.napotherapeutics.com](http://www.napotherapeutics.com).

#### **About Mytesi®**

Mytesi (crofelemer) is an antidiarrheal indicated in the U.S. for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

See full Prescribing Information at [Mytesi.com](http://Mytesi.com). Crofelemer, the active ingredient in Mytesi, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon Rainforest.

#### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that the two crofelemer pipeline development activities on which the company plans to focus over the next 12-15 months will be value-transforming, Jaguar's expectation that investigator-initiated proof-of-concept studies of crofelemer for SBS and CDD will be completed in 2022 and 2023, supporting the potential for expanded patient access through programs in Europe for these diseases and health situations for these patients, Jaguar's plan to complete enrollment of the CTD study in the first half of 2023, Jaguar's expectation that Napo Therapeutics' novel formulation of crofelemer will be more appropriate for SBS patients and will allow for more dosing flexibility for SBS patients, Jaguar's expectation that ODD status in the EU will support Napo Therapeutics' plans to make crofelemer available through Early Access Programs in the EU for SBS, Jaguar's expectation that participation in Early Access Programs will provide a potential opportunity for revenue generation in addition to the ability to impact important morbidity, mortality, and the cost of care for chronically ill patients for whom no therapeutic options exist, and Vision Research Reports' estimate that the global GLP-2 analog market will reach \$4.6 billion by 2027. 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.

<sup>1</sup> Pablo C. Okhuysen, M.D., [The impact of cancer-related diarrhea on changes in cancer therapy patterns: Real world evidence](#)

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