



## Jaguar Health Receives Notice of Allowance for U.S. Patent for Lead FDA Approved Drug Crofelemer

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**Company's IP estate includes approximately 200 patents issued and pending**

**SAN FRANCISCO, CA / ACCESSWIRE / February 23, 2023 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#)** ("Jaguar" or the "Company") today announced that the Company has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for U.S. Patent Application No. 16/617,466, titled *Methods And Compositions For Treating Bile Acid Diarrhea, Diarrhea Associated With Small Intestine Resection Or Gallbladder Removal, And Short Bowel Syndrome*.

"We are very pleased to receive this Notice of Allowance from the USPTO. This Notice of Allowance is expected to conclude the substantive examination of this crofelemer-related patent application and result in the issuance of a U.S. patent after administrative processes are completed," said Steven King, PhD, Jaguar's Chief Sustainable Supply, Ethnobotanical Research, and IP Officer. "Jaguar holds extensive global rights for our crofelemer drug product, comprising a valuable and significant barrier to entry. The Company currently holds approximately 145 issued patents, with coverage in many cases that extends until 2031. These issued patents cover multiple indications including HIV/AIDS-related diarrhea, inflammatory bowel disease (IBD), and irritable bowel syndrome (IBS), as well as important manufacturing processes and other key Company intellectual property. We also currently have approximately 55 pending patent applications worldwide in human health areas that are being prosecuted."

Mytesi<sup>®</sup> (crofelemer) is the Company's antidiarrheal prescription drug approved by the U.S. Food and Drug Administration (FDA) for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. It is the only oral drug approved by the FDA under botanical guidance, providing additional exclusivity advantages.

### **About Crofelemer**

Crofelemer is an oral botanical (plant-based) drug extracted and purified from the red bark sap, also referred to as "dragon's blood," of the *Croton lechleri* tree in the Amazon Rainforest. The Company has established a sustainable harvesting program, under fair trade practices, for crofelemer to ensure a high degree of quality, ecological integrity, and support for Indigenous communities. 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.

### **About Mytesi<sup>®</sup>**

Mytesi (crofelemer) is an antidiarrheal indicated 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](#). 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. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

### **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](http://www.napopharma.com). For more information about Napo Therapeutics, visit [napotherapeutics.com](http://napotherapeutics.com).

### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that this

Notice of Allowance will conclude the substantive examination of this patent application and result in the issuance of a U.S. patent after administrative processes are completed. 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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