



## Jaguar Health Submits Orphan Drug Designation Application to FDA for Crofelemer for Cancer Therapy-Related Diarrhea (CTD) in Patients with Breast Cancer with Metastasis Identified by FDA as a Distinct Condition

September 24, 2025

*Potential treatment for patients with breast cancer with metastasis to the brain with crofelemer would augment the significant responder analysis results for crofelemer in the prespecified subgroup of patients with breast cancer from the [OnTarget](#) study that were reported at the [Multinational Association of Supportive Care in Cancer 2025 Annual Meeting](#) and the 2024 [San Antonio Breast Cancer Symposium](#)*

SAN FRANCISCO, CA / [ACCESS Newswire](#) / September 24, 2025 / [Jaguar Health \(NASDAQ:JAGX\)](#) today announced that Jaguar family company [Napo Pharmaceuticals](#) (Napo) has submitted an [orphan drug designation](#) (ODD) application to the U.S. Food and Drug Administration (FDA) for crofelemer, the company's novel prescription drug, for the treatment of diarrhea in adult patients with breast cancer that has metastasized to the brain receiving targeted therapy with or without standard chemotherapy.

Within the last ten years, the FDA's Office of Orphan Products Development (OOPD) has publicly acknowledged that brain metastasis of any cancer is considered a disease or condition separate and distinct from the primary site of origin. Accordingly, between 2015 and 2024 the OOPD awarded seven orphan drug designations for various therapies for the treatment of breast cancer that has metastasized to the brain.

"The FDA has identified the condition of breast cancer that has metastasized to the brain as an orphan indication. We have submitted this ODD application for crofelemer to treat diarrhea in these patients," said Lisa Conte, Jaguar's founder, president, and CEO. "Diarrhea is a common side effect of numerous targeted cancer therapies that can lead to dose changes, treatment delays, or cessation of treatment altogether, all of which impact patient outcomes. Given crofelemer's novel and physiological mechanism of action, we would plan to seek [Breakthrough Therapy](#) designation and/or [Fast Track](#) designation from the FDA to support potentially expedited regulatory pathways in the U.S. for crofelemer for this indication."

In both the US and European Union, crofelemer has previously received orphan drug designation for short bowel syndrome with intestinal failure and microvillus inclusion disease for a liquid formulation of crofelemer. Crofelemer has also been granted an orphan drug designation for treatment of diarrhea in cholera in the U.S. Orphan drug designation qualifies the drug sponsor for various development and/or regulatory incentives, such as tax credits for qualified clinical testing and relief from filing fees. Furthermore, orphan drug designation in the U.S. provides a seven-year period of marketing exclusivity to the first sponsor.

### About Crofelemer

Crofelemer is a botanical (plant-based) drug extracted and purified from the red bark sap, also referred to as "dragon's blood," of the medicinal *Croton lechleri* tree in the Amazon Rainforest. Jaguar family company Napo Pharmaceuticals 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.

### 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, bowel incontinence, and cramping pain. Jaguar family company Napo Pharmaceuticals (Napo) focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. 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 diseases.

For more information about:

Jaguar Health, visit <https://jaguar.health>

Napo Pharmaceuticals, visit [www.napopharma.com](http://www.napopharma.com)

Napo Therapeutics, visit [napotherapeutics.com](http://napotherapeutics.com)

Visit the *Make Cancer Less Shitty* patient advocacy program on [Bluesky](#), [X](#), [Facebook](#) & [Instagram](#)

### Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that Napo may seek Breakthrough Therapy designation and/or Fast Track designation from the FDA to support potentially expedited regulatory pathways in the U.S. for crofelemer for the treatment of diarrhea in adult patients with breast cancer that has metastasized to the brain. 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.

**CONTACT:**

[hello@jaguar.health](mailto:hello@jaguar.health)

Jaguar-JAGX

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