Jaguar Health Receives Fee Waivers from FDA

September 22, 2026

Company remains sharply focused on its ongoing rare disease intestinal failure global development program for microvillus inclusion disease (MVID) and SBS for crofelemer powder for oral solution, targeting an NDA filing for MVID mid-2027

SAN FRANCISCO, CA / ACCESS Newswire / September 22, 2026 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar) family company Napo Pharmaceuticals (Napo) today announced that the U.S. Food and Drug Administration (FDA) has granted Napo's request for a waiver of the fee associated with the Prescription Drug User Fee Act (PDUFA) for Mytesi® (crofelemer delayed-release tablets) for the 2027 fiscal year. Mytesi is an FDA-approved prescription drug for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy, and is currently commercialized in the U.S. by Future Pak, LLC.

Jaguar was also granted a waiver of the fee by the Center for Veterinary Medicine of the FDA for the 2027 fiscal year for Canalevia®-CA1, Jaguar's conditionally approved prescription drug for the treatment of chemotherapy-induced diarrhea in dogs, which is also commercialized in the U.S. by Future Pak, LLC.

About the Jaguar Health Family of Companies

Jaguar Health, Inc. ("Jaguar") develops novel proprietary prescription drugs sustainably derived from plants for people with complicated gastrointestinal ("GI") disease states. Jaguar family companies Napo Pharmaceuticals, Inc. and Napo Therapeutics S.p.A. focus on the development and commercialization of novel crofelemer powder for oral solution for the treatment of rare and orphan gastrointestinal disorders with intestinal failure, including microvillus inclusion disease and short bowel syndrome. 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, visit https://jaguar.health

Napo Pharmaceuticals, visit napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

About Mytesi®

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.

Important Safety Information About Canalevia®-CA1

For oral use in dogs only. Not for use in humans. Keep Canalevia-CA1 (crofelemer delayed-release tablets) in a secure location out of reach of children and other animals. Consult a physician in case of accidental ingestion by humans. Do not use in dogs that have a known hypersensitivity to crofelemer. Prior to using Canalevia-CA1, rule out infectious etiologies of diarrhea. Canalevia-CA1 is a conditionally approved drug indicated for the treatment of chemotherapy-induced diarrhea in dogs. The most common adverse reactions included decreased appetite, decreased activity, dehydration, abdominal pain, and vomiting.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. **It is a violation of Federal law to**

use this product other than as directed in the labeling. Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-552.

See full Prescribing Information at Canalevia.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that the company will file a New Drug Application (NDA) for crofelemer for MVID in mid-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.

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press release