



Crofelemer, Jaguar Health's Prescription Drug Conditionally Approved by the FDA for Chemotherapy-Induced Diarrhea in Dogs, is the Subject of the Company's Investigational New Animal Drug Application for the Indication of General Diarrhea in Dogs

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SAN FRANCISCO, CA / ACCESSWIRE / May 6, 2024 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) ("Jaguar") today announced that it has established a new Investigational New Animal Drug (INAD) file with the Center for Veterinary Medicine (CVM) of the U.S. Food and Drug Administration (FDA) for the company's novel plant-based prescription drug crofelemer to treat general, non-infectious diarrhea in dogs.

Crofelemer delayed-release tablets, under the name Canalevia[®]-CA1, received conditional approval in December 2021 from the FDA for the treatment of chemotherapy-induced diarrhea (CID) in dogs.

"We're very pleased to have established this new INAD file," said Michael Guy, DVM, MS, PhD, Jaguar's Vice President of Preclinical and Nonclinical Studies. "We've been pleased with the marketplace reception of crofelemer for treatment of CID in dogs, and believe there is clearly an unmet need for a product to treat general, non-infectious diarrhea in dogs as well. We estimate that U.S. veterinarians see approximately six million annual cases of acute and chronic diarrhea in dogs, and we look forward to evaluating the possibility of expanding the indication of crofelemer to include treatment of all types of non-infectious diarrhea in dogs. The next step in our development process is to request a pre-submission conference with the CVM to discuss our proposed protocol for the clinical field study for this new indication."

Jaguar previously issued results from a multicenter, randomized, double-blind, controlled proof-of-concept study that assessed the efficacy of crofelemer administered orally in alleviating clinical signs associated with secretory diarrhea in dogs. The study results showed that crofelemer was superior to placebo.

Diarrhea is one of the most common reasons for veterinary office visits for dogs and is the second most common reason for visits to the veterinary emergency room, yet there are currently no FDA-approved anti-secretory agents to treat canine diarrhea. According to the American Veterinary Medical Association, there were an estimated 83 million to 88 million dogs in the United States in 2020, and 45% of U.S. households owned a dog in 2020. Devastating dehydration can occur rapidly for the animal, and the lack of control in urban settings where owners don't have easy access to outdoor facilities is a significant problem for families with dogs.

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.**

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 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, a 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, visit <https://jaguar.health>

Napo Pharmaceuticals, visit www.napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

Visit Jaguar on LinkedIn: <https://www.linkedin.com/company/jaguar-health/>

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Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." 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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