FDA Approves Renewal of Canalevia-CA1, Jaguar Health's Drug for Chemotherapy-Induced Diarrhea (CID) in Dogs

December 10, 2025

- ***Conditional approval extended through December 2026 for the treatment of CID in dogs***
- ***CID confirmatory effectiveness trial expected to conclude in February 2026, ahead of FDA's June deadline - 51 dogs enrolled to date; ~49 more expected***

SAN FRANCISCO, CA / ACCESS Newswire / December 10, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced that the U.S. Food and Drug Administration (FDA) has granted renewal of the conditional approval for **Canalevia-CA1** (crofelemer delayed-release tablets). Canalevia-CA1, the company's prescription drug for the treatment of chemotherapy-induced diarrhea (CID) in dogs, is available from multiple leading veterinary distributors in the U.S., including **Chewy**. The renewal of conditional approval is in effect until December 21, 2026.

"Canalevia-CA1 is an important prescription drug for the veterinary community and the thousands of dogs experiencing CID. We're very pleased about this conditional approval renewal, which, per FDA regulations, is for the fifth and final allowable year of conditional approval for Canalevia-CA1 for the CID indication in dogs. When an animal drug receives conditional approval, the FDA requires that a confirmatory trial take place within 5 years to provide the substantial evidence of effectiveness required for full approval of the drug for the indication," said Dr. Michael Guy, D.V.M., M.S., Ph.D., Jaguar's Vice President of Preclinical and Nonclinical Studies. "As announced, our full effectiveness study of Canalevia-CA1 for the treatment of CID in dogs is underway, and this recent conditional approval renewal was granted because we were able to demonstrate active progress toward generating this required data."

"Diarrhea is a highly neglected and unmet medical need in dogs and people undergoing cancer treatment," said Lisa Conte, Jaguar's president and CEO. "Jaguar is deeply committed to supporting the quality of life of people and animals undergoing cancer treatment."

About Conditional Approval and Full Approval

Canalevia-CA1 initially received **conditional approval** in December 2021 from the FDA for the treatment of CID in dogs. FDA's conditional approval allows a drug company to legally promote, advertise and sell the animal drug for the labeled uses before proving it meets the "substantial evidence" standard of effectiveness for full approval. The conditional approval is valid for one year, with up to four annual renewals, for a total of five years of conditional approval. To receive a renewal from the FDA, the company must show active progress toward proving "substantial evidence of effectiveness" for full approval. After collecting the remaining effectiveness data, the company then applies to the FDA for full approval. The FDA reviews the application and, if appropriate, fully approves the drug.

About Canalevia®-CA1

Canalevia-CA1 contains crofelemer, Jaguar's novel, oral plant-based drug sustainably harvested from the *Croton lechleri* tree, that modulates chloride channels in the gastrointestinal tract to reduce diarrhea. Importantly, Canalevia is not an antibiotic drug. The overuse and misuse of antibiotics, both in humans and animals, contribute to the development of bacteria that are resistant to antibiotics. Canalevia-CA1, currently conditionally approved by the FDA under application number 141-552, is a tablet that can be given orally twice a day for up to three days and can be used for home treatment of CID in dogs.

About Chemotherapy-induced Diarrhea (CID) in Dogs

According to the American Veterinary Medical Association, approximately 1 in 4 dogs will at some stage in their life develop cancer. Nearly half of dogs over 10 will develop cancer.[1] According to the National Cancer Institute at the National Institutes of Health, roughly 6 million new cancer diagnoses are made in dogs yearly in the US.

Due to the increasing number of chemotherapeutic agents, chemotherapy is fast becoming the most widely used cancer treatment in veterinary medicine. Studies have found the incidence of CID to be one of the three most prevalent side effects in dogs undergoing cancer treatment,[2] and managing side-effects such as diarrhea can be important to maintain successful cancer treatment. More than half of the US veterinarians who responded to a Jaguar-sponsored survey reported that CID interferes with their patients' chemotherapy treatment plans, indicating an unmet need for an effective product for the treatment of CID.

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 (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. 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 napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

Canalevia-CA1, visit 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's ongoing trial will provide the substantial evidence of effectiveness required for full approval of the drug for treatment of CID in dogs and will conclude in February 2026 with an approximate total of 100 dogs having participated. 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.

[1] "Cancer in Pets." American Veterinary Medical Association, 2021, https://www.avma.org/resources/pet-owners/petcare/cancer-pets

[2] Mason SL, Grant IA, Elliott J, Cripps P, Blackwood L. Gastrointestinal toxicity after vincristine or cyclophosphamide administered with or without maropitant in dogs: a prospective randomised controlled study. J Small Anim Pract. 2014;55:391-398

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