Jaguar Health to Pursue Approval of Canalevia in European Union for Treatment of General Diarrhea in Dogs

June 25, 2025

Canalevia® (crofelemer delayed-release tablets), under the name Canalevia-CA1, is conditionally approved by the FDA for treatment of chemotherapy-induced diarrhea in dogs

Jaguar is exploring the possibility of approval of Canalevia for treatment of general diarrhea in dogs in the EU based on the statistically significant data from a completed study

Diarrhea is one of the most common reasons owners bring their dog to the veterinarian and the second most common reason for visits to the veterinary emergency hospital, yet there are currently no FDA-approved drugs to treat general diarrhea in dogs

Company strategy: In discussions with multiple potential animal health company partners to collaborate to bring Canalevia to regulatory approval and commercialization for general diarrhea globally

SAN FRANCISCO, CA / ACCESS Newswire / June 25, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar), under its Jaguar Animal Health tradename for the veterinary market, today announced that the company plans to pursue approval from the European Medicines Agency's (EMA) Committee for Veterinary Medicinal Products (CVMP) for Canalevia (crofelemer delayed-release tablets) in the European Union for treatment of general diarrhea in dogs. Canalevia, under the name Canalevia-CA1, is conditionally approved by the U.S. Food and Drug Administration (FDA) as a prescription drug for the treatment of chemotherapy-induced diarrhea (CID) in dogs.

"Jaguar's primary objective for Canalevia is to identify a partner with which to collaborate to achieve our three parallel goals for the drug: Obtain approval in the EU for Canalevia for treatment of general diarrhea in dogs based on existing Jaguar study data; maintain continuity of availability in the U.S. of Canalevia for treatment of CID in dogs; and to expand the U.S. indication from CID in dogs to treatment of general diarrhea in dogs," said Lisa Conte, Jaguar's Founder and CEO. "I'm pleased to report that Jaguar is currently in discussions with multiple potential animal health company partners to collaborate to bring Canalevia to regulatory approval and commercialization for general diarrhea globally."

Canalevia contains crofelemer, a plant-based botanical prescription drug 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.

"In the EU, it may be possible to obtain approval of Canalevia for treatment of general diarrhea in dogs based on the results of a study Jaguar completed in 200 dogs with general diarrhea," Conte said. "While this trial did not meet its stated primary endpoint, the study results are clinically significant when analyzed using an alternate, simplified endpoint, defining treatment success as any dog that had no episodes of diarrhea following the first treatment with either Canalevia or placebo. Using this revised endpoint, the study data shows that dogs treated with Canalevia had significantly better outcomes - with fewer watery stools and significant improvement in fecal scores compared to placebo-treated dogs."

Jaguar plans to submit a dossier to the European Medicines Agency's (EMA) Committee for Veterinary Medical Products (CVMP) to outline the results of the updated analysis of the company's completed study of Canalevia in dogs with general diarrhea. If acceptable to the EMA, the company will then submit a Marketing Authorization Application (MAA) for Canalevia for general diarrhea in dogs. If the application is approved, Canalevia will be marketable for treatment of general diarrhea in dogs in all 27 EU member countries.

Data from the European Pet Food Industry Federation concluded that there were 104 million dogs in Europe in 2022. "We've been pleased with the marketplace reception of crofelemer for treatment of CID in dogs in the U.S. and believe there is clearly an unmet medical need for a product for the much larger market of treatment of general diarrhea in dogs - both in the U.S. and the EU," said Conte. "We estimate that U.S. veterinarians see approximately six million annual cases of acute and chronic diarrhea in dogs, and we look forward to identifying a partner to fund and execute development and commercialization of crofelemer for the treatment of general diarrhea in the U.S. and/or globally. Forging a partnership for this purpose is a key focus of our business development efforts in 2025 and has been designated as a key potential catalyst for the company this year."

Diarrhea is one of the most common reasons dogs are seen by general practice veterinarians and is the second most common reason for visits to veterinary emergency hospitals, yet there is currently no FDA-approved drug to treat general, non-infectious diarrhea in dogs. According to the American Veterinary Medical Association, there were an estimated 89.7 million dogs in the United States in 2024, with nearly half (45.5%) of U.S. households owning a dog in 2024. Devastating diarrhea-related dehydration can occur rapidly for the animal, and the lack of easy access to outdoor facilities is a significant problem for families living in urban settings with dogs.

Canalevia-CA1, a canine-specific formulation of crofelemer, Jaguar's novel, oral plant-based drug sustainably harvested from the *Croton lechleri* tree, is available from multiple leading veterinary distributors in the U.S., including **Chewy**.

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 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 U.S.

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 U.S. 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.

Canalevia-CA1 is a tablet that can be given orally twice a day and can be used for home treatment of CID in dogs.

About Canalevia®-CA1

Canalevia-CA1 (crofelemer delayed-release tablets) is the first and only oral plant-based prescription product that is FDA conditionally approved to treat chemotherapy-induced diarrhea (CID) in dogs. Canalevia-CA1 is a canine-specific formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. Canalevia-CA1 is currently conditionally approved by the FDA under application number 141-552. Conditional approval allows for commercialization of the product while Jaguar continues to collect the substantial evidence of effectiveness required for full approval. Jaguar has also received Minor Use in a Major Species (MUMS) designation from the FDA for Canalevia-CA1 to treat CID in dogs. FDA has established a "small number" threshold for minor use in each of the seven major species covered by the MUMS act. The small number threshold is currently 80,000 for dogs, representing the largest number of dogs that can be affected by a disease or condition over the course of a year and still have the use qualify as a minor use.

About Crofelemer

Crofelemer is the only oral FDA-approved prescription drug under botanical guidance. It is plant-based, extracted and purified from the red bark sap of the *Croton lechleri* tree in the Amazon Rainforest. Napo Pharmaceuticals, a Jaguar family 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.

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

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 it will pursue approval from the EMA's CVMP for Canalevia in the European Union for treatment of general diarrhea in dogs, Jaguar's expectation that it will identify a partner to fund and execute development and commercialization of crofelemer for the treatment of general, non-infectious diarrhea in dogs in the U.S. and/or globally, Jaguar's expectation that it may be possible to obtain approval of Canalevia in the EU for treatment of general diarrhea in dogs based on the results of the study Jaguar completed in 200 dogs with general diarrhea, Jaguar's expectation that it will submit a dossier to the EMA's CVMP to outline the results of the updated analysis of the company's completed study of Canalevia in dogs with general diarrhea, Jaguar's expectation that, if acceptable to the EMA, the company will then submit a MAA for Canalevia for general diarrhea in dogs, and Jaguar's expectation that, if the MMA is approved, Canalevia will be marketable for treatment of general diarrhea in dogs in all 27 EU member countries. 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

Contact:

hello@jaguar.health
Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

press release