Jaguar Health Makes Submission to EMA Regarding EU Approval Pathway for Canalevia for General Diarrhea in Dogs Based on Data from Completed Study

December 2, 2025

Jaguar's requesting advice from EMA on EU approval pathway for general diarrhea of FDA conditionally approved Canalevia®

A novel non-antibiotic approach to diarrhea treatment is important because there are no FDA-approved drugs to treat general diarrhea in dogs, the second most common reason for visits to veterinary emergency hospitals

SAN FRANCISCO, CA / ACCESS Newswire / December 2, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar), today announced that its Italian subsidiary, Napo Therapeutics S.p.A., has submitted a request to the European Medicines Agency (EMA) to have the EMA's Committee for Veterinary Medicinal Products (CVMP) provide scientific advice regarding the company's plan to pursue approval of Canalevia (crofelemer delayed-release tablets) in the European Union for treatment of general diarrhea in dogs based on data from a study Jaguar completed in 200 dogs in 2017. The request asks that the CVMP review the company's plan and related data during the CVMP's scheduled meeting in March 2026.

The EMA is the EU's equivalent of the U.S. Food and Drug Administration (FDA). Canalevia, under the name Canalevia-CA1, is conditionally approved by the FDA as an oral prescription drug for the treatment of chemotherapy-induced diarrhea (CID) in dogs.

"In the study of 200 dogs with general diarrhea, the pre-specified primary endpoint was not met. However, an updated analysis using a simplified endpoint - defining treatment success as no further episodes of diarrhea after the first treatment - showed that dogs treated with Canalevia had significantly better outcomes than those receiving placebo, including fewer watery stools and improved fecal scores," said Dr. Michael Guy, D.V.M., M.S., Ph.D., Jaguar's Vice President of Preclinical and Nonclinical Studies.

"We provided the CVMP with a summary of the updated analysis of the data from our completed study, which we look forward to having the CVMP review," Dr. Guy said. "Following the start of the procedure in mid-January, the EMA will have 60 days (extendable to 90) to indicate if they agree that this updated analysis would support approval of Canalevia for treatment of general diarrhea in dogs in the EU. If the EMA agrees that the updated analysis would support approval, the company will submit a Marketing Authorization Application to the EMA 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 indicates that there were 69,359,000 dogs in the EU in 2023. According to the American Veterinary Medical Association, there were an estimated 89.7 million dogs in the US in 2024, with nearly half (45.5%) of US households owning a dog in 2024.

"We've been pleased with the marketplace reception of crofelemer for treatment of CID in dogs in the US and see a meaningful opportunity in the much larger market of general diarrhea in dogs, both in the US and the EU. We estimate that US veterinarians see approximately 6 million annual cases of acute and chronic diarrhea in dogs," said Lisa Conte, Jaguar's Founder and CEO. "Our primary objective for Canalevia is to secure a partner to help fund and execute development and commercialization globally for treatment of general diarrhea in dogs, while we continue to support availability for CID in dogs in the US. We have made business development around general diarrhea in dogs a key focus and potential catalyst for Jaguar in 2025."

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. 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.

About Canalevia® and Canalevia®-CA1

Canalevia 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 (crofelemer delayed-release tablets), available from multiple leading veterinary distributors in the US, including **Chewy**, 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 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 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.

Canalevia-CA1 is a tablet that can be given orally twice a day and can be used for home treatment of CID in 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 (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 it may identify a partner to fund and execute development and commercialization of crofelemer for the treatment of general, non-infectious diarrhea in dogs in the US 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, if the submitted summary of the updated analysis of the data from the company's completed study is 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 MAA 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

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SOURCE: Jaguar Health, Inc.

press release