Jaguar Health Receives Notice of $250,000 FDA Grant to Fund Confirmatory Trial to Support FDA Approval of Canalevia for Treatment of Chemotherapy-Induced Diarrhea (CID) in Dogs

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Company strategy: In discussions with multiple potential animal health company partners to expand the indication and commercialize Canalevia for treatment of general diarrhea globally

SAN FRANCISCO, CA / ACCESS Newswire / September 25, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar"), under its Jaguar Animal Health tradename for the veterinary market, today announced that it has received notice from the U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM) of a $250,000 grant. Canalevia, under the name Canalevia-CA1, is currently conditionally approved for chemotherapy-induced diarrhea (CID) in dogs. The grant would support a confirmatory study required for full FDA approval of Canalevia (crofelemer delayed-release tablets) for the treatment of CID in dogs. Acceptance of the award is dependent upon the company's compliance with FDA terms and conditions. The company has not yet accepted the award.

"When an animal drug receives conditional approval, the CVM 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, enrollment has begun in our ongoing full effectiveness study of Canalevia-CA1 for the treatment of CID in dogs. Although we submitted the application for this grant in June 2024, notifications of successful grant awards were delayed due to the new federal administration and funding modifications by the National Institutes of Health. We are planning to request approval from the CVM to use the grant to support this ongoing, slightly modified, field study in dogs undergoing chemotherapy."

"Looking forward, as announced, Jaguar is in discussions with multiple potential animal health company partners regarding collaborating on the development, approval, and commercialization of Canalevia for the expanded indication of treatment of general diarrhea in dogs," said Lisa Conte, Jaguar's Founder and CEO. "Our objective is to partner with an animal health company to achieve three parallel goals for Canalevia: Expand the U.S. indication from CID in dogs to treatment of general diarrhea in dogs; obtain approval in the European Union for Canalevia for treatment of general diarrhea in dogs based on existing Jaguar study data; and maintain continuity of availability in the U.S. of Canalevia for treatment of CID in dogs."

Dogs undergoing chemotherapy are an important predictive model for crofelemer's mechanism of action in humans experiencing diarrhea due to cancer treatment. Many cancer treatment agents provided to dogs are human drugs, or have the same mechanism of action as human cancer drugs, and these agents and mechanisms of action often have meaningful rates of diarrhea in humans as well. As announced yesterday, Jaguar family company Napo Pharmaceuticals has submitted an orphan drug designation application to the FDA for crofelemer for the treatment of diarrhea in adult patients receiving targeted therapy, with or without standard chemotherapy, for breast cancer that has metastasized to the brain.

A report by the American Veterinary Medical Foundation concluded that there were approximately 90 million dogs in the U.S. in 2024, of which Jaguar estimates more than 11 million suffer from general diarrhea each year. Data from the European Pet Food Industry Federation concluded that there were approximately 104 million dogs in Europe in 2022.

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. Canalevia-CA1, a tablet that can be given orally twice a day and can be used for home treatment of CID in dogs, is available from multiple leading veterinary distributors in the U.S., including **Chewy**.

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 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. The drug company can ask the FDA to renew the conditional approval annually for up to four more years, 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, and almost 50% of dogs over age 10 will develop cancer.[1] According to the National Cancer Institute, which is part of the National Institutes of Health, roughly 6 million new cancer diagnoses are made in dogs each year in the U.S.

Due to the increasing number of chemotherapeutic agents being adopted by veterinary oncologists and primary care veterinarians, 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.

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.

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 www.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 request approval from the CVM to use the grant to support the company's ongoing, slightly modified, field study in dogs undergoing chemotherapy, and 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 a study Jaguar completed in dogs with general diarrhea. 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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