First Study Site Established for Jaguar Health Study of its FDA Conditionally Approved Canalevia-CA1 Prescription Drug for Dogs

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Two parallel goals for Canalevia-CA1 (crofelemer delayed-release tablets): To obtain full approval of the drug for treatment of chemotherapy-induced diarrhea (CID) and to expand the indication of crofelemer from CID to treatment of general, non-infectious diarrhea in dogs

Jaguar in discussions with potential partners to license and fund development and commercialization of crofelemer for the treatment of general, non-infectious diarrhea in dogs in the U.S. and/or globally

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

SAN FRANCISCO, CA / ACCESS Newswire / June 11, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar), under its Jaguar Animal Health tradename for the veterinary market, today announced that the first study site has been established for Jaguar's field study of Canalevia-CA1, Jaguar's U.S. Food and Drug Administration (FDA) conditionally approved prescription drug for the treatment of chemotherapy-induced diarrhea (CID) in dogs.

Jaguar has two parallel goals for Canalevia-CA1 (crofelemer delayed-release tablets): To obtain full approval of the drug for treatment of chemotherapy-induced diarrhea (CID) in dogs and to expand the indication of crofelemer from CID in dogs to treatment of general, non-infectious diarrhea in dogs. The company is in discussions with potential partners to fund development and commercialization of crofelemer for the treatment of general, non-infectious diarrhea in dogs in the U.S. and/or globally.

"We've been pleased with the marketplace reception of crofelemer for treatment of CID in dogs, and believe there is clearly an unmet medical need for a product for the much larger market of treatment of general, non-infectious diarrhea in dogs," said Lisa Conte, Jaguar's Founder and CEO. "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, non-infectious 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."

"Jaguar's canine-focused business development efforts align with our ongoing business development efforts on the 'human' side of the company for crofelemer - the catalysts for which are the pathways discussed with the FDA to bring crofelemer to metastatic breast cancer patients, a population we feel meets the requirements for orphan drug status; and the prompt establishment of an expanded access program for crofelemer for the ongoing important unmet medical need of cancer therapy-related diarrhea in breast cancer patients; and the initial proof-of-concept results from the ongoing investigator-initiated trial (IIT) of a novel liquid formulation of crofelemer in Abu Dhabi in pediatric patients with intestinal failure due to the orphan diseases microvillus inclusion disease (MVID) and short bowel syndrome (SBS-IF). As recently announced, the initial proof-of-concept results of this IIT show crofelemer reduced the required total parenteral nutrition (TPN) and/or supplementary intravenous fluids, collectively referred to as parenteral support, in patients with intestinal failure due to MVID and short bowel syndrome by up to 27% and 12.5% respectively."

The objective of the prospective, randomized, open-label field study in dogs undergoing chemotherapy treatment across the U.S. is to collect real-world data to demonstrate real-world evidence of the clinical effectiveness for Canalevia-CA1 for the treatment of CID in dogs to support potential full FDA approval of the drug for this indication. Dogs enrolled in this study will be randomly assigned to receive a prescription of Canalevia-CA1 as a treatment for CID or be randomly selected to the control group.

As announced, Jaguar established a new Investigational New Animal Drug (INAD) file with the FDA's Center for Veterinary Medicine for crofelemer to treat general, non-infectious diarrhea in dogs.

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 drug to treat canine general, non-infectious diarrhea. 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 control in urban settings where owners don't have easy access to outdoor facilities is a significant problem for families 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. 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.

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 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 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 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 the U.S. population of metastatic breast cancer patients meets the requirements for orphan drug status, Jaguar's expectation that it will promptly establish an expanded access program for crofelemer for cancer therapy-related diarrhea in breast cancer patients, and Jaguar's expectation that the field study of Canalevia-CA1 for the treatment of CID in dogs will support potential full FDA approval of the drug for this indication. 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

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