83.33% of Veterinary Oncologists Highlight Importance of Jaguar Health's FDA Conditionally Approved Canalevia-CA1 as a Non-Antibiotic Treatment for Chemotherapy-Induced Diarrhea (CID) in Dog's in New Survey

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Canalevia®-CA1 (crofelemer delayed-release tablets) is the first and only treatment for CID in dogs to receive any type of approval from the FDA

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SAN FRANCISCO, CA / ACCESS Newswire / March 28, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX), under its Jaguar Animal Health tradename for the veterinary market, today announced the results of a new survey of 27 board certified veterinary oncologists practicing in the U.S. regarding Canalevia-CA1 and the treatment of chemotherapy-induced diarrhea (CID) in dogs. Canalevia-CA1, the company's U.S. Food and Drug Administration (FDA) conditionally approved prescription drug product for the treatment of CID in dogs, is available from multiple leading veterinary distributors in the U.S., including Chewy. Of the veterinary oncologists who participated in the survey, 20 (83.33%) indicated that, due to concerns about antibiotic resistance, they felt it was somewhat important to extremely important that Canalevia-CA1 is not an antimicrobial.

"Chemotherapy-induced diarrhea can be challenging to control. Canalevia-CA1 has allowed me to continue anti-cancer therapy in patients in an advanced state of disease while thoroughly managing any GI upset they may experience," said Christine Swanson, DVM, DACVIM (Oncology), a Veterinary Oncologist and Medical Director with BluePearl Specialty + Emergency Pet Hospital.

"As a veterinary oncologist, I recognize the critical role that supportive therapies play in treating cancer in dogs," said Craig Clifford DVM, MS, CACVIM (Oncology). "One challenging side effect is chemotherapy-induced diarrhea, which can significantly impact a dog's quality of life and hinder their ability to tolerate further treatment. Needless to say, the impact also extends to the patient's family in dealing with the aftermath. The novel natural product Canalevia CA-1 significantly advances our approach to managing chemotherapy-induced diarrhea in canine patients. This innovative therapy not only helps to alleviate diarrhea symptoms but may enhance cancer treatment's overall efficacy by allowing dogs to maintain their chemotherapy schedule. By providing a targeted solution that improves gastrointestinal health, this product offers an alternative to metronidazole in this era of microbial stewardship."

"In dogs undergoing chemotherapy, as is the case with people undergoing cancer treatment, diarrhea is a highly neglected and unmet medical need," said Ian Wendt, Jaguar's Chief Commercial Officer. "Jaguar is deeply committed to supporting the quality of life of people and animals undergoing cancer treatment, and Canalevia-CA1 is an important prescription drug for the veterinary community and the thousands of dogs experiencing CID."

Other key highlights of the survey of veterinary oncologists include:

- Of the 24 participants who responded to the question "When managing CID in dogs, which statement best describes your view of metronidazole as a treatment option?", 15 (62.5%) indicated that they are concerned with antimicrobial resistance when treating dogs for CID, and prefer not to use metronidazole for the treatment of CID in dogs.
- Of the 24 participants who responded to the question "When a dog experiences CID, how big of a negative impact does this have on the dog's ability to stay on their index cancer treatment, their quality of life, and the impact on the dog owner?", 16 (66.66%) indicated that they rate CID as having a moderate to large negative impact on a dog's ability to stay on their index cancer treatment, on a dog's quality of life, and on the dog's owner.

While metronidazole, the current standard of care therapy for treatment of CID in dogs, is commonly prescribed for dogs to treat infections and inflammatory conditions that cause diarrhea, these are off-label uses of the medication, as metronidazole is not FDA approved for dogs. Canalevia-CA1 is the first and only treatment for CID in dogs to receive any type of approval from the FDA.

As announced, Jaguar is seeking a partner to fund and execute the development and commercialization of crofelemer, to expand the indication for the treatment of general, non-infectious diarrhea in dogs. The targeted partner would have greater capability to market and promote to the proposed expanded indication of Canalevia in the US.

"We've been pleased with the marketplace reception of crofelemer for treatment of CID in dogs and gratified that both dogs and their families are able to find relief and improved quality of life. We believe there is clearly an unmet need for this plant-based product to treat general, non-infectious diarrhea in dogs as well," Conte said. "We estimate that U.S. veterinarians see approximately six million annual cases of acute and chronic diarrhea 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, 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. Napo's crofelemer is FDA-approved under the brand name Mytesi® for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy. 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." 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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