Jaguar Health Completes Submission of New Animal Drug Application for Full FDA Approval of Crofelemer for Treatment of Chemotherapy-Induced Diarrhea (CID) in Dogs

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Jaguar's recently completed pivotal effectiveness study of crofelemer for the treatment of CID in dogs demonstrates positive, statistically significant results

SAN FRANCISCO, CA / ACCESS Newswire / June 23, 2026 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar") today announced that the company has completed submission of its New Animal Drug Application (NADA) to the U.S. Food and Drug Administration's Center for Veterinary Medicine for full approval of crofelemer for the treatment of chemotherapy-induced diarrhea (CID) in dogs. Crofelemer, under the name Canalevia®-CA1, is currently conditionally approved for this indication in dogs.

"We're very happy to have completed submission of this NADA," said Dr. Michael Guy, D.V.M., M.S., Ph.D., Jaguar's Vice President of Preclinical and Nonclinical Studies. "As announced, the statistically significant results of our recently completed pivotal effectiveness study of Canalevia-CA1 for the treatment of CID in dogs demonstrated that dogs suffering from CID who were treated with Canalevia-CA1 twice daily at the onset of diarrhea had, at the end of 3 days of treatment, an average daily stool that was regarded as normal. Moreover, in a survey at the end of the study, 77% of the owners of dogs participating in the study reported that they believed Canalevia-CA1 was an effective treatment for their dog's CID. Additionally, around 40% of dog owners reported that Canalevia-CA1 completely resolved their dog's CID. In comparison, only 10.5% of owners reported complete resolution in their dog's CID without the use of any CID treatments."

The effectiveness study, which was undertaken at veterinary oncology clinics around the U.S., is a core component of Jaguar's submitted NADA, along with the positive results of a study of crofelemer delayed-release tablets for treatment of cancer therapy-related diarrhea in dogs receiving neratinib - a targeted tyrosine kinase inhibitor (TKI) chemotherapy agent.

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.

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 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 canine patients' chemotherapy treatment plans, indicating an unmet need for an effective product for the treatment of CID.

Important Safety Information About Canalevia®-CA1

For oral use in dogs only. Not for use in humans. Keep Canalevia-CA1 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") develops novel proprietary prescription drugs sustainably derived from plants for people with complicated gastrointestinal ("GI") disease states. Jaguar family companies Napo Pharmaceuticals, Inc. and Napo Therapeutics S.p.A. focus on the development and commercialization of novel crofelemer powder for oral solution for the treatment of rare and orphan gastrointestinal disorders with intestinal failure, including microvillus inclusion disease and short bowel syndrome. 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 weight gain prevention and mental health indications.

For more information about:

Jaguar Health, visit https://jaguar.health

Canalevia-CA1, visit canalevia.com

Napo Pharmaceuticals, visit napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

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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