FDA Approves Renewal of Canalevia-CA1, Jaguar Health's Drug for Chemotherapy-Induced Diarrhea in Dogs

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Canalevia®-CA1 is the first and only treatment for chemotherapy-induced diarrhea (CID) in dogs to receive any type of approval from the FDA

Crofelemer, Jaguar's novel, oral plant-based drug sustainably harvested from the Croton lechleri tree, is the active ingredient in Canalevia-CA1

SAN FRANCISCO, CA / ACCESSWIRE / December 4, 2023 / Jaguar Health, Inc. (NASDAQ:JAGX), under its Jaguar Animal Health tradename for the veterinary market, today announced that the U.S. Food and Drug Administration (FDA) has approved renewal of **Canalevia-CA1** (crofelemer delayed-release tablets). Canalevia-CA1, the company's conditionally approved prescription drug product for the treatment of chemotherapy-induced diarrhea (CID) in dogs, is available from multiple leading veterinary distributors in the U.S., including **Chewy**. The renewal for conditional approval is in effect until December 21, 2024.

"We're very pleased about receiving the conditional approval renewal from the FDA," said Dr. Michael Guy, D.V.M., M.S., Ph.D., Jaguar's vice president of preclinical and nonclinical studies. "This extension was granted because we were able to demonstrate that the company is making active progress toward proving 'substantial evidence of effectiveness' of Canalevia-CA1 for treatment of CID in dogs for full approval, as required. As announced, the company is planning a clinical field study of Canalevia-CA1 to support full approval of the product for the treatment of CID in dogs. Jaguar plans to initiate this study once the company receives the required concurrence from the FDA on the study protocol."

"Diarrhea is a highly neglected and unmet medical need in dogs and people undergoing cancer treatment," said Lisa Conte, Jaguar's president and CEO. "Jaguar is deeply committed to supporting the quality of life of people and animals undergoing cancer treatment."

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 sell the animal drug before proving it meets the "substantial evidence" standard of effectiveness for full approval. The company can also legally promote and advertise the conditionally approved drug for the labeled uses. The conditional approval is valid for one year. The drug company can ask 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 FDA, the company must show active progress toward proving "substantial evidence of effectiveness" for full approval. During the conditional approval period, the company can legally market the animal drug for the labeled uses while collecting the remaining effectiveness data. After collecting the necessary data, the company then applies to FDA for full approval. FDA reviews the application and, if appropriate, fully approves the drug.

About Chemotherapy-induced Diarrhea (CID) in Dogs

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,[1] 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 a full approval. Jaguar has 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 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, and bowel incontinence. Jaguar family company Napo Pharmaceuticals focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo Pharmaceuticals' crofelemer drug product candidate is the subject of the OnTarget study, an ongoing pivotal Phase 3 clinical trial for preventive treatment of chemotherapy-induced overactive bowel (CIOB) in adults with cancer on targeted 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
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Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that it will conduct a clinical field study of Canalevia-CA1 to support full approval of the product for the treatment of CID in dogs, and Jaguar's expectation that it will initiate this study once the company receives the required concurrence from the FDA on the study protocol. 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] 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
Jaguar-JAGX

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