



Jaguar Animal Health Announces Commercial Availability of Plant-based Canalevia-CA1 (Crofelemer) Prescription Drug for the Treatment of Chemotherapy-Induced Diarrhea (CID) in Dogs

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Canalevia[®]-CA1 is the first and only treatment for CID in dogs to receive any type of approval from FDA

SAN FRANCISCO, CA / ACCESSWIRE / April 27, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX), under its Jaguar Animal Health tradename for the veterinary market, today announced that Canalevia-CA1 (crofelemer delayed-release tablets), the company's prescription drug product for the treatment of chemotherapy-induced diarrhea (CID) in dogs, is now available from multiple leading veterinary distributors in the U.S. Canalevia-CA1 [received conditional approval from the FDA](#) on December 21, 2021.

"We are very excited that Canalevia-CA1 is now available to veterinarians across the country," said Chip Whitlow, Sales & Marketing Director of the company's Animal Health Commercial Portfolio. "Canalevia-CA1 is an important prescription drug introduction for the veterinary community and the thousands of dogs experiencing CID. Canalevia-CA1 can help support the comfort and quality of life of dogs while being treated with chemotherapy, which may help keep them compliant with their life-saving treatment."

Due to the increasing number of chemotherapeutic agents being adopted by veterinary oncologists and general practice veterinarians, chemotherapy is quickly becoming the most widely used oncology modality 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 CID can be important to maintain successful cancer treatment. More than half of the U.S. veterinarians who responded to a recent 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.

Jaguar Animal Health launched the www.canalevia.com website in December 2021. For veterinarians, the site provides Canalevia-CA1 prescribing information, data on the pharmacological properties and novel mechanism of action of the product's active pharmaceutical ingredient, crofelemer, and a listing of upcoming veterinary conferences the company plans to attend. For dog owners, the site provides an overview of CID and its negative effects on dogs undergoing chemotherapy.

About Crofelemer

Crofelemer is a novel, oral plant-based medicine extracted and purified from the red bark sap, also referred to as "dragon's blood," of the medicinal *Croton lechleri* tree in the Amazon Rainforest. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, has established a sustainable harvesting program, under fair trade practices, for crofelemer to ensure a high degree of quality, ecological integrity, and support for local and Indigenous communities.

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 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 70,000 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 Jaguar Health, Jaguar Animal Health, Napo Pharmaceuticals, & Napo Therapeutics

Jaguar Health is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Animal Health is a tradename of Jaguar Health. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals from plants harvested responsibly from rainforest areas. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.), an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe.

For more information about Jaguar, please visit <https://jaguar.health>. For more information about Napo Pharmaceuticals, visit www.napopharma.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar Animal Health's expectation that Canalevia-CA1 may help keep dogs compliant with their chemotherapy treatment. 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. Some of the factors that could affect our actual results are included in the periodic reports on Form 10-K and Form 10-Q that we file with the Securities and Exchange Commission. 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

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