Jaguar Health Launches Canalevia-CA1 (Crofelemer) for the Treatment of Chemotherapy-Induced Diarrhea (CID) in Dogs

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The Canalevia.com website, a resource for veterinarians and dog owners, is now live

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

SAN FRANCISCO, CA / ACCESSWIRE / January 4, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced the launch of Canalevia ™-CA1 (crofelemer delayed-release tablets), Jaguar's plant-based prescription drug for the treatment of chemotherapy-induced diarrhea (CID) in dogs. Canalevia-CA1 **received conditional approval from the FDA** on December 21, 2021.

Canalevia-CA1 is being commercialized as a prescription drug product under the company's Jaguar Animal Health tradename. Canalevia-CA1 is a tablet that is given orally and can be prescribed for home treatment of CID.

"We are pleased to have received the first purchase order for Canalevia-CA1 at the end of December, and expect Canalevia-CA1 to be available from multiple leading veterinary distributors in the U.S. later this month," 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 thousands of dogs experiencing CID. Canalevia-CA1 will help support comfort and quality of life while chemotherapy is underway, which may help keep dogs compliant with their life-saving treatment."

Due to the increasing number of chemotherapeutic treatments being adopted by general practice veterinarians and veterinary oncologists, 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 diarrhea 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.

Jaguar launched the **www.canalevia.com** website on December 22, 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 in dogs undergoing chemotherapy.

"We are excited to be formally launching Canalevia-CA1 and making it available to veterinarians across the country," said Michael Guy, DVM, MS, Ph.D., Jaguar's Vice President of Preclinical and Nonclinical Studies. "We will be attending the **2022 Veterinary Meeting & Expo** (VMX) in Orlando, FL January 15-19, the **WVC Annual Conference** in Las Vegas March 6-9, and the **Veterinary Cancer Society Mid-Year Conference** in Puerto Vallarta, Mexico April 9-12, and we look forward to informing attendees about Canalevia-CA1 and the serious impact of CID on dogs."

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 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 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 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, Inc., Jaguar Animal Health, Napo Pharmaceuticals, Inc. & Napo Therapeutics S.p.A.

Jaguar Health, Inc. 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, specifically chronic, debilitating diarrhea. Jaguar Animal Health is a tradename of Jaguar Health. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals from plants harvested responsibly from rainforest areas. Napo Therapeutics S.p.A., the majority owned Italian subsidiary of Napo Pharmaceuticals, 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. For more information about Napo Therapeutics, visit www.napoeu.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that Canalevia-CA1 will be available from multiple veterinary distributors in the U.S. in January 2022, the belief that Canalevia-CA1 may help keep dogs compliant with their chemotherapy treatment, and Jaguar's expectation that it will attend the VMX, WVC, and Veterinary Cancer Society Mid-Year Conference events in 2022. 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

Media Contact:

Peter Hodge
Jaguar Health, Inc.
phodge@jaguar.health
Jaguar-JAGX

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