



Jaguar Animal Health Exhibiting at Veterinary Cancer Society Collaborative Conference for Canalevia-CA1, the Company's FDA Conditionally Approved Drug for Chemotherapy-Induced Diarrhea (CID) in Dogs

March 30, 2023

- **Canalevia[®]-CA1 is the first and only treatment for CID in dogs to receive any type of approval from the FDA**
- **In December 2022, FDA increased the maximum number of dogs that can be treated annually with a conditionally approved animal drug from 70,000 to 80,000**

SAN FRANCISCO, CA / ACCESSWIRE / March 30, 2023 / [Jaguar Health, Inc.](#) (NASDAQ:JAGX) ("Jaguar" or the "Company") under its Jaguar Animal Health tradename for the veterinary market, today announced that the Company is exhibiting at the Veterinary Cancer Society (VCS) Collaborative Conference, which takes place April 19-22, 2023 in Cancun, Mexico, as part of ongoing promotional activities for Canalevia-CA1 (crofelemer delayed-release tablets). Canalevia-CA1, the company's U.S. Food and Drug Administration (FDA) 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.

Effective December 14, 2022, the FDA's Center for Veterinary Medicine increased the maximum number of dogs that can be treated annually with a conditionally approved animal drug from 70,000 to 80,000. "The FDA conducts a [reassessment](#) of the 'small numbers of animals' definition approximately every 5 years," said Michael Guy, DVM, MS, PhD, Jaguar Health's vice president of preclinical and nonclinical studies, "and we're pleased that, as a result of the most recent reassessment, the size of the addressable annual market for Canalevia-CA1 has now increased from 70,000 to 80,000 dogs."

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004

MUMS is modeled on the orphan-drug designation for human drug development. The purpose of the MUMS Act is to encourage the development and availability of animal drugs intended either as a minor use (a use for a disease which occurs infrequently or in limited geographic areas) in a major species (dogs, cats, cattle, horses, chickens, turkeys, and pigs) or for use in minor species (defined as all animals other than humans that are not one of the seven major species).

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, Jaguar Health's wholly owned U.S. subsidiary, 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 Jaguar Health, Jaguar Animal Health, Napo Pharmaceuticals, & Napo Therapeutics

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human pharmaceuticals from plants harvested responsibly from rainforest areas. Our crofelemer drug product candidate is the subject of the [OnTarget](#) study, an ongoing pivotal Phase 3 clinical trial for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. 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. Jaguar Animal Health is a tradename of Jaguar Health.

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

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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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