Jaguar Health Names Principal Investigators for Clinical Trial to Support Full Approval of Canalevia-CA1 for Treatment of Chemotherapy-Induced Diarrhea (CID) in Dogs

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

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

SAN FRANCISCO, CA / ACCESSWIRE / July 26, 2023 / Jaguar Health, Inc. (NASDAQ:JAGX), under its Jaguar Animal Health tradename for the veterinary market, today announced that two leading veterinary oncologists, Laura D. Garrett, DVM, Diplomate ACVIM (Oncology) and Angharad Waite, VMD, DACVIM (Oncology), will serve as Principal Investigators for the company's planned clinical field study of Canalevia®-CA1 (crofelemer delayed-release tablets), the company's U.S. Food and Drug Administration (FDA) conditionally approved prescription drug for the treatment of chemotherapy-induced diarrhea (CID) in dogs, to support full approval of the product.

Canalevia-CA1 received conditional approval in December 2021 from the FDA for the treatment of CID in dogs and is available from multiple leading veterinary distributors in the U.S. Conditional approval allows for commercialization of the product while Jaguar continues to collect the substantial evidence of effectiveness required for full approval.

Laura D. Garrett, DVM, Diplomate ACVIM (Oncology), is a clinical professor in oncology and Specialty Medicine Head at the Veterinary Teaching Hospital at University of Illinois College of Veterinary Medicine. Dr. Garrett received her DVM from the University of Illinois, completed an internship at University of Minnesota, and completed an oncology residency at University of Wisconsin-Madison. After working in a New Zealand specialty clinic, Dr. Garrett was a faculty member at Kansas State University for eight years before she joined the faculty at her alma mater. She is a noted national and international speaker and has published on the topics of canine lymphoma, feline hematology, clinical trials, and communication.

Angharad Waite, VMD, DACVIM (Oncology) is a veterinary medical oncologist with The Oncology Service in Richmond, VA. Dr. Waite graduated from Princeton University magna cum laude and then attended the University of Pennsylvania Veterinary School, obtaining her degree (VMD) in 2008. She stayed on at Penn to complete a rotating small animal internship in medicine and surgery followed by a residency in medical oncology at Cornell University. During the last year of her residency (2012), she received the Small Animal Resident of the Year Award from the fourth-year class.

"Jaguar plans to initiate this clinical fieldstudy of Canalevia-CA1 once the company has received the required concurrence from the FDA on the study protocol," said Michael Guy, DVM, MS, PhD, Jaguar Health's Vice President of Preclinical and Nonclinical Studies. "Canalevia-CA1 is an important prescription drug 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."

The Jaguar Animal Health logo, depicted below, was granted registered trademark status in the US this month.

About Conditional Approval and Full Approval

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

According to the American Veterinary Medical Association, approximately 1 in 4 dogs will, at some stage in their life, develop cancer, and almost 50% of dogs over age 10 will develop cancer.[1] According to the National Cancer Institute, which is part of the National Institutes of Health, roughly 6 million new cancer diagnoses are made in dogs each year in the U.S.

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,[2] 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.

Canalevia-CA1 is a tablet that can be given orally twice a day and can be used for home 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 full approval. Jaguar has also 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 plant-based, extracted and purified from the red bark sap of the *Croton lechleri* tree in the Amazon Rainforest. Jaguar Health company 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.

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, Napo Pharmaceuticals, Napo Therapeutics & Jaguar Animal Health

Jaguar Health 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 company Napo Pharmaceuticals 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 company Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.) is 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." These include statements regarding the company's expectation that Laura D. Garrett and Angharad Waite will serve as Principal Investigators for the company's planned clinical field study of Canalevia-CA1, statements regarding Jaguar's plans to initiate the clinical field study of Canalevia-CA1, and statements regarding receiving 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] "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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