Jaguar Health Announces FDA Conditional Approval of Canalevia-CA1 (Crofelemer), the First and Only Treatment for Chemotherapy-Induced Diarrhea (CID) in Dogs to Receive Any Type of Approval from FDA

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By prescription only, Canalevia ™-CA1 is a canine-specific formulation of crofelemer, Jaguar's novel, oral plant-based product sustainably harvested from the Croton lechleri tree

SAN FRANCISCO, CA / ACCESSWIRE / December 21, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced it received conditional approval to market Canalevia ™-CA1 (crofelemer delayed-release tablets), Jaguar's oral plant-based prescription drug for the treatment of chemotherapy-induced diarrhea (CID) in dogs. This is the first and only product indicated for the treatment of chemotherapy-induced diarrhea (CID) in dogs to receive any type of approval from FDA.

According to the American Veterinary Medical Association, approximately 1 in 4 dogs will, at some stage in their life, develop a tumor, 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 treatments being adopted by 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[2], and managing side-effects such as diarrhea is imperative 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 patient's chemotherapy treatment plan, indicating an unmet need for an effective product for CID.

Canalevia-CA1 will be marketed as a prescription drug product under the company's Jaguar Animal Health tradename. Jaguar will be sharing more details surrounding the commercialization plan for Canalevia-CA1 in early January 2022.

"We are thrilled to be filling a large gap in the canine cancer care field by providing relief to thousands of dogs and pet owners across the country who thankfully can benefit greatly from advances in canine cancer treatments, yet also have to manage the burden of diarrhea as a common side effect," said Lisa Conte, Jaguar's President and CEO and parent of two Jack Russell Terriers. "In a third-party survey of dog and cat owners, the majority of participants (58%) indicated that they believed that the benefits of chemotherapy did not counterbalance the impact of the potentially negative side effects which animals may experience during treatment.[3] Canalevia-CA1 provides another option to address the comfort of dogs undergoing chemotherapy and supports the dog's ability to maintain control, which is important for maintaining a comfortable living environment in the family household."

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." 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]"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

[3]Williams J, Phillips C, Byrd HM. Factors Which Influence Owners When Deciding to Use Chemotherapy in Terminally Ill Pets. *Animals (Basel)*. 2017;7(3):18. Published 2017 Mar 7. doi:10.3390/ani7030018

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