Jaguar Health Shares Comments from FDA's December 21 Press Release About Conditional Approval of Canalevia-CA1 (Crofelemer) for Treatment for Chemotherapy-Induced Diarrhea (CID) in Dogs

December 22, 2021

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 22, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) today shared the following quote from the press release the U.S. Food and Drug Administration (FDA) issued December 21, 2021: "Diarrhea is a common side effect of chemotherapy in dogs, which can be so severe that cancer treatment must be halted. Chemotherapy drugs often have potential side effects, but, unlike in human medicine where patients may be willing to tolerate some discomfort in exchange for a potential cure, the primary purpose of cancer treatment in dogs and other pets is to extend survival without sacrificing quality of life and comfort," said Steven M. Solomon, D.V.M., M.P.H., director of the FDA's Center for Veterinary Medicine. "This new medication provides veterinarians and dog owners with another tool to help control the side effects of chemotherapy for dogs undergoing such treatment."

The full FDA press release can be viewed by clicking **here**.

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.

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