Jaguar Animal Health Seeks MUMS Designation from FDA for Canalevia (Crofelemer) for Treatment of Exercise-induced Diarrhea (EID) in Dogs

February 16, 2022

In December of 2021, FDA conditionally approved Canalevia ™-CA1 for treatment of chemotherapy-induced diarrhea in dogs, and the company expects Canalevia could receive FDA conditional approval, under the name Canalevia ™-CA2, for treatment of EID in dogs

SAN FRANCISCO, CA / ACCESSWIRE / February 16, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX), under its Jaguar Animal Health tradename for the veterinary market, today announced that it has submitted a request to the U.S. Food and Drug Administration's Center for Veterinary Medicine for Minor Use/Minor Species (MUMS) designation for the company's oral plant-based drug candidate Canalevia ™ (crofelemer) for treatment of exercise-induced diarrhea (EID) in dogs.

"MUMS designation is a status similar to 'orphan drug' status for human drugs, and it makes the proposed intended use of a MUMS drug eligible for specific incentives supporting product approval or conditional approval. Receipt of MUMS designation for Canalevia for EID in dogs would make the company eligible to apply for Federal grants related to development costs, and provide the company with a longer period (seven years) of marketing exclusivity following conditional approval of Canalevia for EID in dogs," said Dr. Michael Guy, DVM, MS, Ph.D., Jaguar Health's vice president of preclinical and nonclinical studies. "Canalevia, under the name Canalevia ™-CA1, has received MUMS designation for chemotherapy-induced diarrhea (CID) in dogs, and we believe Canalevia also meets the requirements for MUMS designation for our planned EID indication in dogs."

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

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

In December of 2021, Jaguar Animal Health received conditional approval from the FDA for Canalevia ™-CA1 for CID in dogs, and the company expects that Canalevia could receive FDA conditional approval, under the name Canalevia ™-CA2, for treatment of EID in dogs in the fourth quarter of 2022.

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. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A., an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe.

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 www.napotherapeutics.com.

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.**

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the company's expectation that Canalevia could receive FDA conditional approval, under the name Canalevia-CA2, for treatment of EID in dogs in the fourth quarter of 2022, and the company's belief that Canalevia also meets the requirements for MUMS designation for the planned EID indication in dogs. 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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SOURCE: Jaguar Health, Inc.

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