



Jaguar Health Completes Filing of New Animal Drug Application for Conditional Approval of Canalevia-CA1 (Crofelemer) to Treat Chemotherapy-Induced Diarrhea in Dogs, Clearing Way for December 2021 Launch

November 2, 2021

Canalevia™-CA1 is the first and only oral plant-based prescription drug candidate for CID in dogs
Jaguar kicks off educational awareness contest in honor of International Jaguar Day; Click [here](#) to enter

SAN FRANCISCO, CA / ACCESSWIRE / November 2, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced that it has completed the filing of the New Animal Drug Application (NADA) to request the U.S. Food and Drug Administration's conditional approval to market Canalevia™-CA1 (crofelemer delayed-release tablets), Jaguar's oral plant-based prescription drug candidate for the treatment of chemotherapy-induced diarrhea (CID) in dogs.

"All required major and minor technical sections of our application for conditional approval of Canalevia for CID in dogs have been deemed 'Complete' by the CVM, and filing of the NADA is an administrative activity that results in approval for commercialization 60 days later. We are therefore now planning for the commercialization of Canalevia-CA1 for CID in dogs in late-December 2021," said Michael Guy, DVM, MS, Ph.D., Jaguar's vice president of preclinical and nonclinical studies.

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. For the most part, dogs receive human chemotherapeutic agents during treatment and suffer the same side effects as humans, which means approximately 40% of treated dogs may have their chemotherapy reduced, changed, or discontinued due to diarrhea - which can compromise the full benefit of the chemotherapy agent.

Chemotherapy is evolving to become the most widely-used oncology treatment modality in veterinary medicine. Moreover, the most prevalent and used targeted chemotherapy, tyrosine kinase inhibitors (TKIs), with substantial rates of diarrhea, are widely becoming adopted by small animal practitioners.

There currently are no FDA-approved medications for the symptomatic treatment of CID in dogs.

"Treating CID is important to influence the outcome of a dog's cancer treatment, by allowing them to maintain a therapeutic dose, and to help with patient comfort and the dog's ability to maintain control, which is important for the home - the rug, couches, and general living environment," said Lisa Conte, Jaguar's president and chief executive officer and parent of two Jack Russell Terriers. "This has been a year of pandemic dogs, with dog ownership increasing in the U.S. They are important members of the family."

In addition to CID in dogs, Jaguar also plans to seek conditional approval from the CVM to market Canalevia for the treatment of exercise-induced diarrhea (EID) in dogs in 2022.

Canalevia-CA1 will be marketed as a prescription drug product of the company's Jaguar Animal Health business unit. Crofelemer, the active ingredient in Canalevia-CA1, comes from the *Croton lechleri* tree, which is responsibly and sustainably harvested in South America.

Jaguar Kicks Off Educational Awareness Contest in Honor of International Jaguar Day

In honor of International Jaguar Day (November 29, 2021), we've dedicated this sixth educational awareness contest in our series to jaguars. These majestic animals have long played a central role in the ecology, cosmology, and shamanic traditions of multiple Indigenous peoples in Central and South America, as described in a wonderful book, [An Indomitable Beast](#), by one of the world's pre-eminent jaguar and large cat conservationists and scientists, [Dr. Alan Rabinowitz \(@DrRabinowitz\)](#). Dr. Rabinowitz, may he rest in peace, passed away in 2018. A copy of *An Indomitable Beast* is the prize for this contest.

The winner will be chosen at random from the pool of contest participants who correctly answer all or most questions in the multiple-choice form. Entries must be received by 9:00 a.m. US Eastern Time on November 26, 2021. No fee is required to enter the contest. Additional contest terms and conditions apply. Click [here](#) to enter and for contest terms and conditions.

Stay tuned to the "Jaguar Health Community" page on Instagram (<https://www.instagram.com/jaguarhealthcommunity/>) to view the contest winner's name, view the answers to the contest questions, and learn about future contests.

About Jaguar Health, Inc., Napo Pharmaceuticals, Inc. & Napo EU 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. Our 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 EU S.p.A., the substantially 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 EU, visit www.napoeu.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that Canalevia will be available under conditional approval for CID in late-December 2021 and for EID in dogs in 2022. 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.

CONTACT:

Peter Hodge
Jaguar Health, Inc.
phodge@jaguar.health

Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

accesswire.com

<https://www.accesswire.com/670543/Jaguar-Health-Completes-Filing-of-New-Animal-Drug-Application-for-Conditional-Approval-of-Canalevia-CA1-Crofelemer-to-Treat-Chemotherapy-Induced-Diarrhea-in-Dogs-Clearing-Way-for-December-2021-Launch>