Jaguar Health Receives "Complete" Letter from FDA for Last of Four Major Technical Sections for the Company's Application for Conditional Approval of Canalevia (Crofelemer) for Chemotherapy-Induced Diarrhea (CID) in Dogs

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Jaguar planning for launch of Canalevia ™ for CID in dogs this December

Canalevia is the first and only oral plant-based prescription drug candidate for CID in dogs

SAN FRANCISCO, CA / ACCESSWIRE / September 23, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced that it was informed on September 21, 2021 by the FDA's Center for Veterinary Medicine (CVM) that the Target Animal Safety (TAS) technical section of the company's application for conditional approval of Canalevia for chemotherapy-induced diarrhea (CID) under the Minor Use/Minor Species (MUMS) section of The Minor Use and Minor Species Animal Health Act of 2004 has been deemed "Complete". The TAS section - the last of the four major technical sections of Jaguar's application - describes testing undertaken to show that a drug candidate is safe for use under the conditions for which the drug will be prescribed following its approval.

Canalevia (crofelemer delayed-release tablets) is Jaguar's oral plant-based prescription drug candidate for the treatment of CID in dogs.

"All four of the required major technical sections of our application for conditional approval of Canalevia for CID in dogs have now been deemed 'Complete' by the CVM. Filing of the New Animal Drug Application (NADA) to request conditional approval from the CVM to market Canalevia for this indication will follow our receipt of a 'Complete' letter for the minor 'Labeling' technical section of the application. Filing of the NADA is an administrative activity that will result in conditional approval 60 days later, and we are planning for the launch of Canalevia for CID in dogs in December 2021," said Michael Guy, DVM, MS, Ph.D., Jaguar's vice president of preclinical and nonclinical studies.

On average, more than 500,000 dogs in the U.S. are diagnosed with cancer each year. 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 limit the ability of the veterinarian to extract the full benefit of the chemotherapy agent.

Due to the increasing number of chemotherapeutic procedures being adopted by general practice veterinarians and veterinary oncologists, 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), 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 - as well helping the dog to maintain control, which is important for the home - the rug, couches, and general living environment - for the dog parent and family," said Lisa Conte, Jaguar's president and chief executive officer and parent of two Jack Russell Terriers. "This is 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," Dr. Guy added. "With a successful NADA for EID in dogs, Canalevia could be available under conditional approval for this additional indication in 2022."

Crofelemer, Canalevia's active ingredient, comes from the *Croton lechleri* tree, which is responsibly and sustainably harvested in South America.

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 wholly owned Italian subsidiary of Napo Pharmaceuticals, focuses on expanding crofelemer access in Europe and is the named target of Dragon SPAC S.p.A., which closed its financing in July 2021 for gross proceeds of approximately 8,830,000 euros from Jaguar.

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 Jaguar's expectation that Canalevia could be available under conditional approval for CID in December 2021 and for EID in dogs in 2022, and the belief that approximately 40% of dogs undergoing chemotherapy for cancer may have their chemotherapy reduced, changed or discontinued due to diarrhea. 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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