

# Jaguar Health Issues Regulatory Update Regarding Potential Indication for Crofelemer in Dogs

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# Company's Legacy Animal Health Business Supports Focus on Human Health Benefits

SAN FRANCISCO, CA / ACCESSWIRE / August 26, 2019 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") announced today that the Company is scheduled to meet with the U.S. Food & Drug Administration's Center for Veterinary Medicine (CVM) on September 11, 2019 to conduct a pre-submission conference about the Company's plans to evaluate crofelemer for exercise-induced diarrhea (EID) in dogs.

To expedite the submission and application process for the EID indication, Jaguar will be leveraging use of the same four major technical sections for EID that have been or will be submitted in support of the Company's application for crofelemer delayed-release tablets (Canalevia <sup>™</sup>) for the indication of chemotherapy-induced diarrhea (CID) in dogs, which is proceeding on a parallel development path in support of conditional approval.

As announced June 19, 2019, the Target Animal Safety technical section, which is the last of the four technical sections Jaguar is required to file for the proposed CID indication, is expected to be submitted to CVM in the third quarter of 2019.

"We believe dog experience, such as the recent crofelemer study in dogs with an FDA-approved human tyrosine kinase inhibitor (TKI), is predictive of the expected benefit of crofelemer in human patients suffering from cancer therapy-related diarrhea. With receipt of conditional approval for CID, the Company expects the product to be commercially available for this indication in dogs in the first half of 2020," Lisa Conte, Jaguar's president and CEO, stated.

EID is a common problem among working dogs, such as sled dogs and military dogs, when subjected to periods of intense, long-duration off-leash exercise.

"Elite athletes of all species tend to have more diarrhea than their healthy but more sedentary counterparts, and while the episodes of diarrhea may not be life-threatening, they are nevertheless significant if the goal is peak physical performance. Thus, there is a considerable need in the world of working dogs for products that can reduce the incidence and severity of exercise-induced diarrhea without affecting performance," commented Dr. Michael Davis, DVM, Ph.D., DACVIM, DACVSMR, a veterinary physiologist and board-certified specialist in veterinary internal medicine and veterinary sports medicine at Oklahoma State University, where he conducts research on animal exercise physiology and performance.

#### **About Crofelemer**

Crofelemer, the active pharmaceutical ingredient being tested, is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal *Croton lechleri* tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

## About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas.

For more information about Jaguar, please visit jaguar, health. For more information about Napo, visit napopharma.com.

### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that the Company will meet with CVM on September 11, 2019, the expectation that the Target Animal Safety technical section of the Company's application for conditional approval of Canalevia for CID in dogs will be submitted to CVM in the third quarter of 2019, the belief that dog experience, such as the recent crofelemer study in dogs with an FDA-approved human TKI, is predictive of the expected benefit of crofelemer in human patients suffering from cancer therapy-related diarrhea, and the expectation that the Company will conduct the commercial launch of Canalevia for CID in dogs, if the Company receives conditional approval for this indication, in the first half of 2020. 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. 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

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