Jaguar Health Files Final Canalevia (Crofelemer) Technical Section for Proposed Indication of Chemotherapy-Induced Diarrhea in Dogs

October 1, 2019

Reminder: Company to Host Investor Call October 3rd at 8 a.m. Eastern to Provide Updates Regarding Development of Mytesi® (Crofelemer) for the Potential Follow-on Indication of Cancer Therapy-Related Diarrhea in Humans

SAN FRANCISCO, CA / ACCESSWIRE / October 1, 2019 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") announced today that on September 30, 2019, the Company filed the Target Animal Safety technical section with the U.S. Food & Drug Administration's Center for Veterinary Medicine (CVM) for Jaguar's application for conditional approval of Canalevia™ (crofelemer delayed-release tablets) for chemotherapy-induced diarrhea (CID) in dogs. This technical section is the last of the four major technical sections Jaguar is required to file for conditional approval of Canalevia for the proposed CID indication.

"As previously announced, the CVM has already indicated that Jaguar's Reasonable Expectation of Effectiveness Technical Section and Environmental Sections are complete for use of Canalevia for treatment of CID," Dr. Michael Guy, DVM, MS, PhD, Jaguar's vice president and clinical veterinarian, commented. "With receipt of conditional approval for this indication, we expect to conduct the commercial launch of Canalevia for CID in dogs in the first half of 2020."

Lisa Conte, Jaguar's president and CEO, stated, "Since our July 2017 merger with Napo Pharmaceuticals, as previously announced, Jaguar's human portfolio has been, and continues to be, our core focus. However, CID is an interesting model for human medical need and is being pursued as our first prescription indication for animal health. We believe there is an important unmet medical need for the treatment of CID in dogs. Certain cancer treatment agents provided to dogs are human drugs, or have the same mechanism of action as human cancer drugs, and these agents and mechanisms of action often have meaningful rates of diarrhea in humans as well. Canalevia acts locally in the gut and is minimally absorbed systemically. It does not alter gastrointestinal motility, has no significant effects on normally-functioning intestinal ion channels or the transport of electrolytes or fluids, and has no side effects different from placebo. These features are further augmented by the lack of effects of Canalevia on the absorption and/or metabolism of co-administered chemotherapy drugs, orally or by other routes of administration."

Canalevia, Jaguar's lead veterinary drug product candidate, is a canine-specific oral formulation of crofelemer, an active pharmaceutical ingredient (API) isolated and purified from the *Croton lechleri* tree, which is sustainably harvested.

As previously announced, Jaguar has received Minor Use/Minor Species (MUMS) designation, per the requirements of The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act), for Canalevia for CID in dogs. To obtain conditional approval of a MUMS drug, a company must submit Chemistry, Manufacturing and Controls (CMC), Environmental Impact, and Target Animal Safety data identical to that required for a new animal drug application (NADA) as well as data suggesting a reasonable expectation of effectiveness. After the submission and the review of the application, the FDA through the CVM can then grant a conditional approval (CA-1). This approval allows for commercialization of the product, while the sponsor continues to collect the substantial evidence of effectiveness required for a full NADA approval. A sponsor that gains approval or conditional approval for a MUMS-designated drug then receives seven years of marketing exclusivity.

MUMS designation is modeled on the orphan-drug designation for human drug development and offers possible financial incentives to encourage MUMS drug development, such as the availability of grants to help with the cost of developing the MUMS drug and a longer period of marketing exclusivity. The purpose of the MUMS Act is to encourage development and availability of animal drugs intended as a minor use in a major species (defined as 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).

As previously announced, Jaguar now has two separate indications for Canalevia (crofelemer) being considered for Conditional Approval by the CVM. The second proposed indication is for exercise-induced diarrhea (EID) in dogs. Jaguar will be leveraging use of the same major technical sections for EID that have been submitted in support of the Company's application for Canalevia for the indication of CID in dogs.

Dial-In Instructions for Conference Call

When: October 3, 2019 at 8 a.m. Eastern Time

Dial-in (US Toll Free): 888-394-8218

Dial-in (International): 323-701-0225

Conference ID number: 5256435

Live webcast on the investor relations section of Jaguar's website (click here)

Replay Instructions

Dial-in (US Toll Free): 844-512-2921

Dial-in (International): 412-317-6671

Replay Pin Number: 5256435

Replay of the webcast on the investor relations section of Jaguar's website (click here)

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. Our Mytesi® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

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

About Mytesi®

Mytesi (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

See full Prescribing Information at Mytesi.com. Crofelemer, the active ingredient in Mytesi, 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.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that the Company will host an investor call October 3rd at 8 a.m. Eastern, the expectation that, if Canalevia receives conditional approval for the indication of CID in dogs, Jaguar will conduct the commercial launch of Canalevia for CID in dogs in the first half of 2020, the belief that there is an important unmet medical need for the treatment of CID in dogs, and the Company's plans to leverage use of the same major technical sections for EID that have been submitted in support of the Company's application for Canalevia for the indication of CID 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.