Jaguar Health Enters Exclusive Crofelemer License and Commercialization Agreement with SynWorld Technologies for Canalevia for Treatment of Diarrhea in Dogs in China

June 29, 2022

License fees of $5.0 million, and up to $5.0 million in unregistered equity infusion, over next 24 months

Service agreement of up to $5.0 million payable in unregistered Jaguar stock to SynWorld to support approval of crofelemer in China, providing Jaguar Health with up to 80% of profits

SAN FRANCISCO, CA / ACCESSWIRE / June 29, 2022 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar) today announced that the company has entered an exclusive license and services agreement with Ontario, Canada-based SynWorld Technologies Corporation (SynWorld) for the treatment of diarrhea in dogs in the China market with Jaguar's Canalevia® (crofelemer delayed-release tablets) prescription drug product.

"We are very excited about the possibility of making Canalevia available in China as part of the license we have provided to SynWorld for crofelemer for treatment of diarrhea in dogs in this territory," said Lisa Conte, Jaguar's founder, president, and CEO. "Per the terms of the agreement, Jaguar is engaging SynWorld as a service provider to obtain regulatory approval of the product for Jaguar in China and granting SynWorld a license to commercialize and sell this product following such approval in China. As consideration for the license, Jaguar is entitled to receive 60% of any profits from sales of the product in China. If Jaguar reimburses SynWorld for the direct expense of obtaining regulatory approval in China, the profit sharing will be 80% and 20%, respectively, for Jaguar and SynWorld."

The agreement also entails monthly license fee payments by SynWorld to Jaguar amounting to US $5.0 million in total during the initial two-year term of the agreement, and a commitment by SynWorld to make quarterly purchases of Jaguar common stock (purchased at market price in unregistered stock at the time of purchase), amounting to US $5.0 million of Jaguar stock purchased in total, during the initial two-year term of the agreement. As consideration for the regulatory services to be provided by SynWorld, Jaguar will pay SynWorld a monthly service fee up to U.S. $5.0 million in total over the initial two-year term of the agreement in the form of unregistered Jaguar stock, with the value of such stock equal to market price at the time of such issuance. Under no circumstances will stock under the agreement be issued below market price on the commencement date of the license agreement. Additionally, under no circumstances will the number of shares of common stock issued under the agreement (i) exceed 19.99% of the total Jaguar shares outstanding as of the date of the agreement or (ii) result in the total number of shares of common stock held by SynWorld and its affiliates exceeding 19.99% of total Jaguar shares outstanding at any given time, in each case unless stockholder approval is obtained. The agreement includes customary termination provisions including the right of either party to terminate the agreement for material breach of the agreement by the other party.

"We are especially pleased with the infusion of capital into Jaguar expected over time from this agreement. This anticipated contribution to Jaguar's financial health not only supports these efforts to expand Canalevia availability to China, it will support Jaguar's goal of realizing value from progress in the development of the human pipeline of crofelemer, specifically: (i) the targeted completion of enrollment by the end of Q2, 2023 for the OnTarget Phase 3 study of crofelemer for the prophylaxis of cancer therapy-related diarrhea; and (ii) the completion and publication of proof-of-concept data for the orphan indications of short bowel syndrome (SBS) and potentially congenital diarrheal disorders (CDD) in 2022, supporting potential approval from the European Medicines Agency for early patient access to product in the European Union for SBS and CDD - an effort led by Napo Therapeutics, the rare disease-focused company Jaguar established in Europe in 2021 that has an exclusive license to crofelemer in Europe," said Conte.

Crofelemer, under the name Canalevia®-CA1, **received conditional approval from the U.S. Food and Drug Administration** on December 21, 2021 for the treatment of chemotherapy-induced diarrhea (CID) in dogs in the United States, and Jaguar is currently pursuing FDA conditional approval of Canalevia for treatment of exercise-induced diarrhea (EID) in dogs in the US. This license agreement has the potential to significantly improve and/or expand the value of Jaguar's Canalevia-related intellectual property portfolio.

According to Frost & Sullivan's *2018 China Pet Industry Report*, there were approximately 74 million pet dogs in China at the end of 2018, the number of pet-owner households in China increased from 69.3 million in 2013 to 99.8 million in 2018, and ***the market size of China's overall pet industry is projected to reach an estimated RMB472.3 billion (US $70.5 billion) by 2023 - an 800 percent increase compared to 2013.***

"The Chinese pet market has been expanding very rapidly, thanks to fast-rising pet ownership driven by a younger generation of consumers who view dogs and cats as embedded members of the family," said Tao Wang, SynWorld's General Manager, "and this growth is projected to continue. We look forward to creating a sales channel for the Chinese pet market and plan to directly sell Canalevia through already-existing sales and distribution partnerships in China following approval of the product in this territory."

About Crofelemer

Crofelemer is a novel, oral plant-based medicine extracted and purified from the red bark sap, also referred to as "dragon's blood," of the medicinal *Croton lechleri* tree in the Amazon Rainforest. Jaguar's wholly owned subsidiary, Napo Pharmaceuticals, has established a sustainable harvesting program, under fair trade practices, for crofelemer to ensure a high degree of quality, ecological integrity, and support for local and Indigenous communities.

About Canalevia®-CA1

Canalevia-CA1 (crofelemer delayed-release tablets) is the first and only plant-based prescription product that is FDA conditionally approved to treat chemotherapy-induced diarrhea (CID) in dogs. Canalevia-CA1 is an oral formulation of crofelemer, an active pharmaceutical ingredient isolated and purified from the *Croton lechleri* tree. Canalevia-CA1 is currently conditionally approved by the FDA under application number 141-552. Conditional approval allows for commercialization of the product while Jaguar continues to collect the substantial evidence of effectiveness required for a full approval. Jaguar has received Minor Use in a Major Species (MUMS) designation from the FDA for Canalevia-CA1 to treat CID in dogs. FDA has established a "small number" threshold for minor use in each of the seven major species covered by the MUMS act. The small number threshold is currently 70,000 for dogs, representing the largest number of dogs that can be affected by a disease or condition over the course of a year and still have the use qualify as a minor use.

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.**

About SynWorld Technologies Corporation

SynWorld Technologies Corporation employs cutting edge technology to facilitate opportunities for companies in the U.S. to reach international markets, specifically, China. This is particularly important for publicly traded U.S. based companies who need distribution and Chinese compliance-related logistic partnerships.

About Jaguar Health, Jaguar Animal Health, Napo Pharmaceuticals, & Napo Therapeutics

Jaguar Health 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, including chronic, debilitating diarrhea. Jaguar Animal Health is a tradename of Jaguar Health. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, 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. (f/k/a Napo EU 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, please visit https://jaguar.health. For more information about Napo Pharmaceuticals, visit www.napopharma.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that regulatory approval will be obtained for Canalevia (crofelemer delayed-release tablets) for treatment of diarrhea in dogs in China, the expectation that an infusion of capital into Jaguar will occur over time as a result of this agreement and that this anticipated contribution to Jaguar's financial health will support Jaguar's goal of realizing value from progress in the development of the human pipeline of crofelemer, the expectation that enrollment will complete by the end of Q2 2023 for the OnTarget study, the expectation that proof-of-concept data for SBS and potentially CDD will be completed and published in 2022, supporting potential approval from the European Medicines Agency for early patient access to product in the European Union for SBS and CDD, the expectation that the agreement has the potential to significantly improve and/or expand the value of Jaguar's Canalevia-related intellectual property portfolio, the expectation that the market size of China's overall pet industry will reach an estimated RMB472.3 billion (US $70.5 billion) by 2023, SynWorld's expectation that growth in the Chinese pet market will continue, and SynWorld's expectation that it will create a sales channel for the Chinese pet market and directly sell Canalevia through already-existing sales and distribution partnerships in China following approval of the product in China. 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/706886/Jaguar-Health-Enters-Exclusive-Crofelemer-License-and-Commercialization-Agreement-with-SynWorld-Technologies-for-Canalevia-for-Treatment-of-Diarrhea-in-Dogs-in-China