Jaguar Health Announces that Orphan Drug Designation Application Submitted to the FDA for Crofelemer for a Severe Congenital Diarrheal Disorder (CDD) Has Been Accepted for Review

August 23, 2022

Microvillus Inclusion Disease (MVID), a CDD, Is a Life-Threatening and Rare Autosomal Recessive Disease That Affects Newborns and Children and Leads to Significant Morbidity and Mortality From Severe Secretory Diarrhea

Replay Link for Jaguar's August 22, 2022 Investor Webcast Can Be Accessed by Clicking Here; Q2 2022 Represented the Fourth Consecutive Quarter of Growth in Mytesi® Net Revenue

SAN FRANCISCO, CA / ACCESSWIRE / August 23, 2022 / Jaguar Health (NASDAQ:JAGX) today announced that its Orphan Drug Designation (ODD) application for crofelemer submitted to the U.S. Food and Drug Administration for a rare congenital diarrheal disorder called microvillus inclusion disease (MVID) has been accepted by the FDA for review. A response from the FDA on the application is expected by the end of September 2022.

Jaguar today also provided the replay link for the company's August 22, 2022 investor webcast, which can be accessed by clicking **here**.

"Although our message may have been lost with the overall market turndown yesterday, we were very pleased to announce that our prescription product net revenue was approximately $2.9 million in the second quarter of 2022, representing an increase of approximately 12% over Mytesi net revenue in the first quarter of 2022, which totaled approximately $2.6 million, and an increase of approximately 641% over Mytesi net revenue in the second quarter of 2021, which totaled approximately $0.4 million," said Lisa Conte, Jaguar's president and CEO. "This is the FOURTH consecutive quarter of growth in Mytesi net revenue - which largely represents the funds collected after various insurance and government chargebacks. The continued improvement in net revenue - a key reportable financial measure of commercial performance under GAAP (generally accepted accounting principles) - is largely a result of the efficiencies realized by the transition we completed this past January to a closed network of specialty pharmacies - an initiative that resulted in a meaningful reduction in Mytesi distribution costs as well as a higher average net price."

As announced, Napo Therapeutics, the Italian corporation Jaguar established in Italy in 2021 that focuses on expanding crofelemer access in Europe with an initial focus on orphan designated diseases, submitted an ODD application for crofelemer this past May for MVID to the European Medicines Agency (EMA).

"CDDs are a group of inherited chronic enteropathies characterized by heterogeneous etiology, and each type of CDD is thus a different disease with a different pathogenetic mechanism," said Martire Particco, MD, Chief Medical Officer of Napo Therapeutics. "MVID is a life-threatening and rare autosomal recessive disease that affects newborns and children and leads to significant morbidity and even death from severe secretory diarrhea."

CDDs share a primary common symptom: chronic diarrhea, and therefore secondary symptoms associated with diarrhea, including significant dehydration, metabolic acidosis or alkalosis and malnutrition, among other secondary symptoms, and these symptoms expeditiously emerge and become life-threatening.

Napo Therapeutics' mission is to provide access to Jaguar's proprietary first-in-class plant-based medicine crofelemer in Europe to address such significant rare disease indications. Under its license to crofelemer from Jaguar, Napo Therapeutics' initial focus is on clinical development and future registration in Europe of crofelemer for debilitating orphan disease target indications, starting with short bowel syndrome (SBS) and CDD.

Crofelemer has received ODD from the EMA and the FDA for SBS, which is a complex condition characterized by severe malabsorption of fluids and nutrients due to surgical resection of bowel segments, congenital anomalies, or disease-associated loss of absorption. For SBS patients who endure the catastrophic loss of their bowel, the resulting excessive intestinal fluid output and lifelong restriction and adjustment of oral intake of food and liquids leads to the requirement to receive intravenous fluids for most of every day (parenteral nutrition). This challenges their ability to carry out activities of daily living, or to attend school or work, and has a significant impact on their daily quality of life. Furthermore, lifelong parenteral nutrition leads to potentially life-threatening complications like sepsis and organ failure. SBS affects approximately 10,000 to 20,000 people in the United States[1], according to the Crohn's & Colitis Foundation, and it is estimated that the population of SBS patients in Europe is approximately the same size.[2]

Jaguar anticipates the completion in 2022 of an investigator-initiated proof-of-concept study of crofelemer for SBS, supporting the potential for expanded patient access to crofelemer in Europe in 2023 for this disease. The company has approved this planned trial of crofelemer for SBS, and the third-party investigator is targeting the presentation in December 2022 of results from the SBS study at a global GI conference in Dubai.

About Crofelemer

Crofelemer is a botanical (plant-based) drug 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. Napo Pharmaceuticals, Jaguar Health's wholly owned U.S. subsidiary, has established a sustainable harvesting program, under fair trade practices, for crofelemer to ensure a high degree of quality, ecological integrity, and support for Indigenous communities.

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

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, including chronic, debilitating diarrhea. Jaguar Animal Health is a tradename of Jaguar Health. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human 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 Health, 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 the company's expectation that a response from the FDA on the CDD ODD application will be received by the end of September 2022, the company's expectation that an investigator-initiated proof-of-concept study of crofelemer for SBS will be completed in 2022, the company's expectation that the results of this SBS study will support the potential for expanded patient access to crofelemer in Europe in 2023 for SBS, and the expectation that the third-party investigator for this SBS study will present the study results in December 2022 at a global GI conference in Dubai. 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.

[1] http://www.crohnscolitisfoundation.org/sites/default/files/legacy/assets/pdfs/short-bowel-disease-crohns.pdf

[2] http://www.pharmabiz.com/NewsDetails.aspx?aid=84221&sid=2

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