Orphan Drug Designation Application Submitted by Jaguar Health Subsidiary for Crofelemer for Short Bowel Syndrome with Intestinal Failure Accepted for Review by European Medicines Agency

September 15, 2021

The conditional marketing authorization pathway in Europe for crofelemer for this orphan disease is the initial focus of Napo EU under the license agreement between Napo EU and Napo Pharmaceuticals

Jaguar to host investor webcast Monday, September 20th at 8:30 a.m. Eastern; Click here to register for webcast

SAN FRANCISCO, CA / ACCESSWIRE / September 15, 2021 / Jaguar Health (NASDAQ:JAGX) today announced that the European Medicines Agency (EMA) has confirmed that the Orphan Drug Designation (ODD) application for crofelemer submitted by Napo EU S.p.A., the Italian subsidiary of Napo Pharmaceuticals (Jaguar's wholly owned U.S. subsidiary), for the indication of short bowel syndrome with intestinal failure (SBS-IF) has been accepted for review. Confirmation from the EMA that the submission is accepted starts the formal review process of the application by the EMA's Committee for Orphan Medicinal Products (COMP).

Napo EU's initial focus is on pursuing the EMA's conditional marketing authorization pathway in Europe (excluding Russia) for crofelemer for this important orphan disease indication.

The evaluation process for the ODD application takes approximately 90 days from acceptance for review. Sponsors who obtain orphan designation for their drug can benefit from Scientific Advice from the EMA for clinical trials for the orphan indication and receive market exclusivity for a period of ten years once the medicine is approved for commercialization.

"We are very happy that the orphan drug designation application for crofelemer for SBS-IF is now with the EMA," stated Lisa Conte, Jaguar's president and CEO and Napo EU board member. "Looking forward, upon receipt of a positive opinion from the COMP, crofelemer will be eligible for granting of orphan drug designation by the EMA for this indication. Receipt of orphan drug designation would support a conditional marketing authorization pathway for SBS-IF, which provides a fast-track review of a medicine that fulfills an unmet medical need."

As announced on August 19, 2021, Napo has signed a license agreement with Napo EU to study, develop, and commercialize crofelemer in the European Union and in specified non-EU countries in Europe for specific indications. The agreement grants Napo EU the right to study, develop, and commercialize crofelemer in this geographic region for SBS-IF, HIV-related diarrhea, and the symptomatic relief and treatment of intestinal failure in patients with congenital disorders, and the right to license additional potential indications. The license agreement includes up-front license fees, milestone payments, royalties, and transfer pricing of product.

Crofelemer has previously received an orphan-drug designation in the U.S. from the Food and Drug Administration 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]

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 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. Crofelemer is the active ingredient in Mytesi®, Jaguar's FDA approved drug to treat diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). It is the only oral plant-based prescription medicine approved under FDA Botanical Guidance.

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. 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 and the only oral plant-based prescription medicine approved under FDA Botanical Guidance. 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.

About Mytesi®

Mytesi® (crofelemer delayed release tablets) 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%).

More information and complete Prescribing Information are available at Mytesi.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the Company's expectation that it will host an investor webcast on September 20, 2021. 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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