# Napo EU S.p.A., Jaguar Health's Italian Subsidiary, Provides Updates on Plans to Pursue Conditional Marketing Authorization in the EU

June 1, 2021

***Jaguar & Dragon SPAC announce initial funding of $10.8 million into Dragon SPAC***

***Napo EU to focus initially on conditional approval for an important orphan indication, short bowel syndrome (SBS), a condition leading to intestinal failure***

***Innovators with Jane King webcast interview with Jaguar CEO Lisa Conte & Dragon SPAC founding sponsor Josh Mailman to take place Thursday, June 3rd at 8:30 AM Eastern***

***Registration link for webcast appears below***

***Equita Group S.p.A., a leading Italian based investment bank, advising Dragon SPAC; Cantor Fitzgerald & Co. advising Jaguar on non-deal related activities***

**SAN FRANCISCO, CA & MILAN, ITALY / ACCESSWIRE / June 1, 2021 /** Napo EU S.p.A. ("Napo EU"), the Italian subsidiary of Napo Pharmaceuticals, Inc. ("Napo Pharma"), which is a wholly owned subsidiary of Jaguar Health, Inc. (NASDAQ: JAGX) ("Jaguar" or the "Company"), today provided updates on plans to pursue conditional marketing authorization from the European Medicines Agency ("EMA") for crofelemer, the Company's novel proprietary drug. Additionally, Jaguar and Milan, Italy-based Dragon SPAC S.p.A. ("Dragon SPAC") today announced the first funding of the Dragon SPAC private financing in an amount equal to approximately $10.8 million, with proceeds of such financing to be used in part for Dragon SPAC's contemplated business combination with Napo EU.

Napo EU was formed with the mission to expand access to crofelemer to Europe to address significant unmet gastrointestinal medical needs, and Napo EU's initial focus is on pursuing conditional marketing authorization for an important orphan indication: short bowel syndrome ("SBS"). SBS is a complex condition characterized by severe malabsorption of fluids and nutrients due to surgical resection of substantial lengths of bowel segments, congenital anomalies, or disease-associated loss of absorption.

In the European Union (EU), a drug is defined as rare/orphan if it treats a life-threatening or chronically and seriously debilitating condition affecting fewer than 5 in 10,000 people across the EU. An orphan designation allows a pharmaceutical company to benefit from incentives from the EU, such as reduced fees and protection from competition once the medicine is placed on the market.

Napo Pharma previously received orphan-drug status for crofelemer from the Office of Orphan Products Development (OOPD) of the U.S. Food and Drug Administration ("FDA") for a potential future SBS indication in adult and/or pediatric patients. Napo Pharma intends to simultaneously pursue regulatory approval to commercialize the new formulation of crofelemer in the U.S. for SBS.

The FDA is committed to advancing rare disease therapies through the Orphan Drug Act (ODA) of 1983, providing financial and other incentives for innovation to treat rare diseases. Since this groundbreaking legislation went into effect, more than 300 orphan products for treatment of rare diseases have been approved in the U.S. by the FDA.

"For SBS patients who suffer from 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 that patients receive intravenous fluids for most of every day - a treatment called parenteral support ("PS"). 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 PS leads to potentially life-threatening complications like sepsis," Darlene Horton, M.D., Napo's Chief Medical Officer, said. "Orphan drug designation is one of the most important areas of drug regulatory incentives that exists today."

According to the Crohn's & Colitis Foundation, approximately 10,000 to 20,000 people in the United States have SBS[1], and it's estimated that the population of SBS patients in Europe is approximately the same size.[2] Many of these patients are reliant on parenteral support.

It is estimated that the direct costs of inpatient PS in Europe ranges from approximately €28,000 to €75,000 (approximately $34,000 to $91,000 per patient per year[3-5]) and that home parenteral nutrition costs 30%-60% less than the cost of PS in the hospital[6]. The estimated annual cost for non-hospitalized PS for an SBS patient in the U.S. is approximately $150,000[7]. Additional indirect PS costs include hospitalisations, infections, laboratory tests, and the need for a multi-disciplinary care team which can further increase health care resource utilization.

A treatment that can delay or reduce an SBS patient's reliance on PS will offer significant value to the patient in terms of disease management and

quality of life and offer significant cost savings to the healthcare system. The global SBS market exceeded $568 million in 2019 and is expected to reach $4.6 billion by 2027 with a CAGR of 26% from 2020 to 2027, according to a report from Vision Research Reports.

"We are quite pleased that Napo EU is the named target of Dragon SPAC and that Dragon SPAC has completed a first funding for the benefit of Napo EU," stated Lisa Conte, Napo EU's sole board member and the founder, president, and CEO of Jaguar and Napo Pharma. "Napo EU has refined its business plan, and the terms of its contemplated license from Napo Pharma, to focus initially on conditional approval for SBS. Although our initial focus was on addressing diarrhea in COVID long-hauler patients, there is growing evidence that long-hauler symptoms may be ameliorated following vaccination against COVID-19. While Napo EU will continue to monitor the COVID long-hauler population to determine if diarrhea remains a chronic condition, we believe focusing on SBS represents a more substantial and long-term initial opportunity for Napo EU to help patients with significant unmet medical needs. Plans are in place to develop a new dosage form of crofelemer that will be optimized for SBS patients and would, we believe, be eligible to pursue the EMA's conditional marketing authorization pathway for orphan medicines for this indication."

**Participation Instructions for Webcast**

When: Thursday, June 3rd at 8:30 AM Eastern Time

Participant Registration & Access Link: **Click Here**

**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 Pharmaceuticals' wholly owned Italian subsidiary, Napo EU S.p.A., 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. For more information about Napo EU, visit www.napoeu.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%).

More information and complete Prescribing Information are available 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 Napo EU's plans to pursue conditional marketing authorization for SBS, Napo Pharma's intention to pursue regulatory approval to commercialize a new formulation of crofelemer in the U.S. for SBS, the Company's belief that focusing on SBS represents a more substantial and long-term initial opportunity for Napo EU to help patients with significant unmet medical needs, plans to develop a new dosage form of crofelemer that will be optimized for SBS patients, the belief that the new dosage form of crofelemer will be eligible to pursue the EMA's conditional marketing authorization pathway for orphan medicines for this indication, and the Company's expectation that a webcast interview event will take place June 3, 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

[3]Aatmani TDK, et al. Gastroenterol Clin Biol 2006;30:574-79

[4]Arhip L, et al. Clin Nutr. 2019;38(4):1945-51

[5]Howard L. Gastroenterology. 2006;130(2 Suppl 1):S52-9

[6]https://int.shortbowelsupport.com/hcp/burden-of-disease/costs-of-sbs-if-care

[7]https://nutritionequity.org/wp-content/uploads/2018/05/mnea-factsheet-sbs.pdf

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