



Jaguar Health's Subsidiary Napo EU Changes Name to Napo Therapeutics, Reflecting the Italian Company's Focus on Rare Diseases & Orphan Drugs

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SAN FRANCISCO, CA / ACCESSWIRE / December 20, 2021 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced that the name of its majority owned subsidiary changed from Napo EU S.p.A. to Napo Therapeutics S.p.A. effective December 17, 2021. Napo Therapeutics is a European specialty drug development and marketing company based in Milan, Italy.

"Our mission at Napo Therapeutics is to provide access to Jaguar Health's proprietary first-in-class plant-based medicine crofelemer in Europe to address significant rare disease indications - and our initial focus is on clinical development and future registration in Europe of crofelemer for two debilitating orphan target indications: Short bowel syndrome with intestinal failure (SBS-IF) and congenital diarrheal disorders (CDD). We believe Napo Therapeutics will support and facilitate expanded and accelerated patient access to a novel therapy. The name-change to Napo Therapeutics reflects our focus on rare diseases and orphan-drugs," commented Massimo Mineo, General Manager of Napo Therapeutics.

Crofelemer is a novel, plant-based oral chloride ion channel modulator that boasts a unique anti-secretory mechanism of action, acting locally in the gastrointestinal tract to modulate and normalize the patient's waterflow.

"Normal functioning of the small intestine is crucial to optimize a patient's absorption of fluids and nutrients to support life. Crofelemer's ability to regulate ion channels in the gut normalizes the salt and water balance in the small intestine, which may lead to better absorption of fluids and nutrients in those living with SBS-IF," Mr. Mineo said.

Napo Therapeutics is pursuing the accelerated conditional marketing authorization pathway from the European Medicines Agency (EMA) for crofelemer for short bowel syndrome (SBS) under orphan-drug designation (ODD).

As announced December 13, 2021, the EMA has granted ODD for crofelemer for the SBS indication in the European Union following review of the ODD application Napo Therapeutics submitted to the EMA this past September. Following this decision from the EMA, Napo Therapeutics is initiating efforts to plan and commence a pivotal clinical trial of crofelemer in both adult and pediatric SBS patients in support of the company's key focus on pursuing the EMA's accelerated conditional marketing authorization pathway in Europe for this rare disease. Crofelemer previously received ODD in the U.S. from the U.S. Food and Drug Administration for SBS.

About Short Bowel Syndrome (SBS)

SBS 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 U.S.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 Despite limited treatment options, the global SBS market exceeded \$568 million in 2019 and is expected to reach \$4.6 billion by 2027, according to a report by Vision Research Reports.

"We believe that crofelemer's first-in-class mechanism of action may potentially benefit and change the lives of people suffering from this devastating rare disease," added Mr. Mineo.

CDD refers to a group of inherited enteropathies with a typical onset early in life. Infants with CDD experience frequent chronic diarrhea of sufficient severity to require parenteral nutrition.

About Jaguar Health, Inc., Napo Pharmaceuticals, Inc. & Napo Therapeutics 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 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 crofelemer drug product candidate is the subject of the OnTarget study, an ongoing pivotal Phase 3 clinical trial for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. Napo Therapeutics S.p.A., the majority owned Italian subsidiary of Napo Pharmaceuticals, 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 Therapeutics, visit www.napoeu.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the belief that Napo Therapeutics will support and facilitate expanded and accelerated patient access to a novel therapy, the expectation that crofelemer's ability to regulate ion channels in the gut may lead to better absorption of fluids and nutrients in those living with SBS-IF, the expectation that Napo Therapeutics will commence a pivotal clinical trial of crofelemer in both adult and pediatric SBS patients, the expectation that the global SBS market may reach \$4.6 billion by 2027, and the belief that crofelemer's first-in-class mechanism of action may potentially benefit and change the lives of people suffering SBS. 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 several 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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