



European Medicines Agency Grants Orphan Drug Designation for Crofelemer to Napo EU, Jaguar Health's Italian Subsidiary, for Short Bowel Syndrome

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The recognition of Orphan Drug Designation in Europe for crofelemer for this rare disease is the first key milestone of Napo EU under the company's exclusive license agreement with Jaguar Health

SAN FRANCISCO, CA and MILAN, ITALY / ACCESSWIRE / December 13, 2021 / Jaguar Health (NASDAQ:JAGX) and its majority owned Italian subsidiary, Napo EU S.p.A. (soon to be renamed Napo Therapeutics), today announced that the European Commission has adopted the decision to grant Orphan Drug Designation (ODD) for crofelemer for the indication of short bowel syndrome (SBS) in the European Union following review of the ODD application Napo EU submitted to the European Medicines Agency (EMA) this past September.

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.

"Following this very welcome decision from the EMA, Napo EU is initiating efforts to plan and commence a pivotal clinical trial of crofelemer in both adult and pediatric SBS patients in support of our key focus on pursuing the EMA's accelerated conditional marketing authorization pathway in Europe for this debilitating rare disease," said Massimo Mineo, General Manager of Napo EU.

"SBS is a devastating disease. The mortality rate of SBS patients on home parenteral nutrition is about 30% after 5 years³, and it is estimated that approximately 70% of SBS patients in Europe are pediatric," stated Lisa Conte, Jaguar's president and CEO and Napo EU board member. "The accelerated approval regulatory pathway in Europe is key to our strategy underlying the exclusive license Jaguar Health has provided to Napo EU for crofelemer and to our efforts to make crofelemer's novel mechanism of action available to patients suffering from rare diseases like SBS in the most rapid manner. Additionally, Jaguar Health has the right to utilize any clinical or regulatory data generated by Napo EU for SBS on a global basis, which provides us with another potential and important 'shot on goal' for crofelemer."

Jaguar Health's exclusive license agreement with Napo EU provides a perpetual, royalty-bearing license for Europe (excluding Russia), and includes traditional terms such as up-front fees, milestone payments, royalties on sales in Europe, and a supply agreement. Jaguar Health owns a majority equity stake in Napo EU.

Crofelemer has previously received orphan drug designation 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 the ability of SBS patients 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.

About Crofelemer

Crofelemer is a novel, oral plant-based medicine 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.

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. Napo EU S.p.A., the wholly 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 EU, visit www.napoeu.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that Napo EU will commence a pivotal clinical trial of crofelemer in both adult and pediatric SBS patients. 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>

³Schalamon J, Mayr JM, Höllwarth ME. Mortality and economics in short bowel syndrome. Best Pract Res Clin Gastroenterol. 2003;17(6):931-942. doi:10.1016/s1521-6918(03)00079-9

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