



## **Jaguar Health Announces Plan to Develop and Commercialize Crofelemer, the Company's Novel Proprietary Drug, for the Indication of Inflammatory Diarrhea, Initially in 'Long-Hauler' COVID-19 Recovery Patients**

November 30, 2020

***A significant percentage of COVID-19 recovery patients suffer from long-term diarrhea or other gastrointestinal dysfunctions***

***Non-binding terms to fund activities in Europe***

**SAN FRANCISCO, CA / ACCESSWIRE / November 30, 2020 /** Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar" or the "Company") and the Company's wholly-owned subsidiary, Napo Pharmaceuticals, Inc. (Napo), announced today that Jaguar and Napo are planning to develop and commercialize crofelemer, the Company's novel proprietary drug, for an indication of prophylaxis and/or symptomatic relief of inflammatory diarrhea, initially to be studied in a 'long-hauler' COVID-19 recovery patient population in Europe.

As part of this plan, the Company is engaged in preliminary discussions with Swiss Growth Forum, a sponsor of a European special purpose acquisition company, "Post Pandemic Recovery Equity" ("the SPAC"), regarding the SPAC's potential merger with an operational subsidiary of the Company to be established in Europe with an exclusive license to crofelemer and Mytesi<sup>®</sup> for the indications of inflammatory diarrhea and HIV-related diarrhea. The preliminary terms under discussion include an upfront cash license fee to Napo ranging from approximately \$2.0 million to \$10.0 million; funding for the European operation of at least \$20 million to pursue clinical development of crofelemer for inflammatory diarrhea in a long-hauler COVID-19 recovery patient population; and equity ownership in the European subsidiary by Napo ranging from 30% to 49.9% post-acquisition by the SPAC, with lower equity ownership in conjunction with a higher up-front cash license fee received by Napo. Other customary financial terms include royalties and transfer pricing on the supply of crofelemer and Mytesi to the European operation.

Management of Jaguar is currently on a road show in Europe with Swiss Growth Forum seeking support for the anticipated European operation identified as a target for the Post Pandemic Recovery Equity SPAC, for which Swiss Growth Forum is a promoter.

The terms "long-hauler" and "chronic COVID" refer to COVID-19 survivors who suffer with symptoms which may include gastrointestinal distress (i.e. diarrhea, constipation, nausea, pain), fatigue, brain fog, forgetfulness, cardiovascular effects, and arthritis, for an extended period after recovery. It is theorized that these symptoms may result when the immune system in COVID-19 survivors continues to overreact even though the infection has passed. Long-hauler syndrome appears to be predominant in younger COVID-19 recovery patients and those who experienced a mild/asymptomatic case.

Inflammation in the GI track often manifests as diarrhea, and chronic diarrhea may be an observable symptom that can provide for early diagnosis of long-hauler syndrome. Early diagnosis of chronic COVID syndrome could help limit the burden of long-term chronic illness in COVID-19 recovery patients.

"Our focus on the new potential indication of prophylaxis and/or symptomatic relief of inflammatory diarrhea for crofelemer is driven primarily by the emergence of the long-hauler COVID-19 recovery patients," Lisa Conte, Jaguar's president and CEO, commented. "Enteropathy, an inflammatory chronic syndrome typically affecting long-term HIV/AIDS survivors, brings on chronic diarrhea. We believe this situation is analogous to what we're seeing right now in COVID-19 recovery patients who are suffering from long-term diarrhea or other gastrointestinal dysfunctions."

Endpoints being explored for possible clinical trials of crofelemer would include prophylaxis and/or symptomatic relief of diarrhea, reduction in inflammatory gut markers, gut biome restoration, and reduction in viral fecal shedding.

"Our exploratory discussions with Swiss Growth Forum in the European Post Pandemic Recovery Equity SPAC matches well to our intention to focus clinical exploration for this development project in Europe, where single-payer healthcare systems focus on preventative measures to diagnose and treat symptoms that can be a precursor to potentially chronic illness," Conte said. "It is estimated that up to 25% of people in the United Kingdom, for example, have already been infected with SARS-CoV-2, the virus that causes COVID-19, and it appears to be the general consensus that around 30% of COVID-19 patients end up suffering from long-hauler syndrome," added Conte. "With infection rates growing the way they are, we believe it's possible that 10% to 15% of the global population is at risk of experiencing long-hauler syndrome."

Napo has conducted intellectual property filings in support of the development of crofelemer for the potential indication of addressing inflammatory diarrhea, including specifically in a long-hauler post-COVID recovery situation. As with all potential follow-on indications, Napo prioritizes IP protection. Napo currently holds approximately 144 patents, the majority of which do not expire until 2027 - 2031, and approximately 39 patents pending.

Mytesi<sup>®</sup> (crofelemer) is a novel, first-in-class anti-secretory agent which has a basic normalizing effect locally on the gut, and this mechanism of action

has the potential to benefit multiple disorders. Mytesi is a non-opiate, plant-based, chloride ion channel modulating antidiarrheal medicine that is approved in the U.S. by the Food and Drug Administration (FDA) for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy.

The only oral plant-based prescription medicine approved under FDA Botanical Guidance, Mytesi is also in development for multiple possible follow-on indications, including cancer therapy-related diarrhea, a rare disease indication for adult patients with short bowel syndrome (SBS), supportive care for inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), and idiopathic/functional diarrhea. As previously disclosed, Napo initiated its pivotal Phase 3 clinical trial of crofelemer (Mytesi) for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy ("cancer therapy-related diarrhea" (CTD)) this past October. Crofelemer in pediatric liquid formulation is in development for a rare disease indication for infants and children with congenital diarrhea disorders (CDD) and pediatric SBS.

#### **About Jaguar Health, Inc. and Napo Pharmaceuticals, Inc.**

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<sup>®</sup> (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.

For more information about Jaguar, please visit <https://jaguar.health>. For more information about Napo, visit [www.napopharma.com](http://www.napopharma.com).

#### **About Mytesi<sup>®</sup>**

Mytesi<sup>®</sup> (crofelemer) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi<sup>®</sup> is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi<sup>®</sup>. 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](http://Mytesi.com). Crofelemer, the active ingredient in Mytesi<sup>®</sup>, 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 the expectation that Jaguar and Napo plan to develop and commercialize crofelemer, the Company's novel proprietary drug, for an indication of prophylaxis and/or symptomatic relief of inflammatory diarrhea, initially to be studied in a long-hauler COVID-19 recovery patient population in Europe, the SPAC's potential merger with an operational subsidiary of the Company to be established in Europe with an exclusive license to crofelemer and Mytesi for the indications of inflammatory diarrhea and HIV-related diarrhea, the Company's belief that chronic diarrhea may be an observable symptom that can provide for early diagnosis of long-hauler syndrome, the Company's belief that early diagnosis of chronic COVID could help limit the burden of long-term chronic illness in COVID-19 recovery patients, the Company's expectations regarding possible endpoints for possible clinical trials of crofelemer in Europe, and development efforts related to other possible Mytesi or crofelemer follow-on indications. 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.

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