



Issuance of New US Patent Bolsters IP Protection for Jaguar Health in the Treatment of Congenital Diarrheal Disorders (CDDs)

January 4, 2024

New patent issued for core rare disease target indication for crofelemer

Jaguar is supporting investigator-initiated proof-of-concept studies of crofelemer for the rare disease indications of microvillus inclusion disease - an ultrarare CDD - and short bowel syndrome (SBS) in the US, EU, and Middle East/North Africa regions, with results expected in 2024

SAN FRANCISCO, CA / ACCESSWIRE / January 4, 2024 / [Napo Pharmaceuticals](#) (Napo), a [Jaguar Health \(NASDAQ:JAGX\)](#) (Jaguar) family company, today announced that the United States Patent and Trademark Office on January 2, 2024 issued a new U.S. patent to Napo for methods for treating congenital diarrheal disorders (CDDs) in patients with an inhibitor of chloride-ion transport such as crofelemer, Napo's novel plant-based prescription drug.

"We are very happy that this patent has been issued and believe that it further enhances our intellectual property protection for crofelemer for our core focus on CDD indications," said Lisa Conte, Jaguar's founder, president, and CEO.

Jaguar is supporting investigator-initiated and investigator IND proof-of-concept studies of crofelemer for the rare disease indications of microvillus inclusion disease (MVID) - an ultrarare CDD - and short bowel syndrome (SBS) in the US, European Union, and Middle East/North Africa (MENA) regions, with results expected in 2024. In accordance with the guidelines of specific EU countries, published data from such clinical investigations could support reimbursed early patient access to crofelemer for MVID or SBS for these debilitating conditions.

MVID is a catastrophic medical situation for pediatric patients, and there are currently no approved drug treatments.

Some SBS patients are subject to intestinal failure, often requiring parenteral nutrition (PN) from a few to up to 7 days a week. Intestinal failure is associated with significant morbidity and mortality; and high medical expenses associated with PN. SBS patients with intestinal failure also have severe chronic diarrhea, and the associated sequelae from diarrhea, including significant dehydration, metabolic acidosis or alkalosis and malnutrition, and other secondary symptoms, and these symptoms emerge either early or late, and many times become life-threatening.

Crofelemer has been granted Orphan Drug Designation (ODD) by the FDA and the European Medicines Agency for both MVID and SBS with intestinal failure. The ODD programs in the US and EU qualify sponsors to receive potential incentives to develop therapies for the diagnosis, prevention, or treatment of rare diseases or conditions.

As with all potential follow-on indications, Jaguar and Napo prioritize IP protection. Napo currently holds approximately 148 patents and approximately 50 patents pending. To date, crofelemer is the only oral plant-based prescription medicine approved under the FDA's Botanical Guidance, which provides an important additional exclusivity advantage due to the inherent practicalities limiting the pathway by which a generic version of the drug could be produced.

About Crofelemer

Crofelemer is a novel, oral plant-based prescription medicine purified from the red bark sap, also referred to as "dragon's blood," of the *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 the Jaguar Health Family of Companies

Jaguar Health, Inc. (Jaguar) is a commercial stage pharmaceuticals company focused on developing novel proprietary prescription medicines sustainably derived from plants from rainforest areas for people and animals with gastrointestinal distress, specifically associated with overactive bowel, which includes symptoms such as chronic debilitating diarrhea, urgency, bowel incontinence, and cramping pain. Jaguar family company Napo Pharmaceuticals focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo Pharmaceuticals' crofelemer drug product candidate is the subject of the [OnTarget](#) study, an ongoing pivotal Phase 3 clinical trial for preventive treatment of chemotherapy-induced overactive bowel (CIOB) in adults with cancer on targeted therapy. Jaguar family company Napo Therapeutics is an Italian corporation Jaguar established in Milan, Italy in 2021 focused on expanding crofelemer access in Europe and specifically for orphan and/or rare diseases. Jaguar Animal Health is a Jaguar tradename. Magdalena Biosciences, a joint venture formed by Jaguar and Filament Health Corp. that emerged from Jaguar's [Entheogen Therapeutics Initiative](#) (ETI), is focused on developing novel prescription medicines derived from plants for mental health indications.

For more information about:

Jaguar Health, visit <https://jaguar.health>

Napo Pharmaceuticals, visit www.napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

Visit Jaguar on LinkedIn: <https://www.linkedin.com/company/jaguar-health/>

Visit Jaguar on X: https://twitter.com/Jaguar_Health

Visit Jaguar on Instagram: <https://www.instagram.com/jaguarhealthcommunity/>

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that results of investigator-initiated and investigator IND proof-of-concept studies of crofelemer for MVID and SBS will be available in 2024, and Jaguar's expectation that, in accordance with the guidelines of specific EU countries, published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID. 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.

Contact:

hello@jaguar.health

Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

press.releaseaccesswire.com