FDA-Authorized Expanded Access Programs Utilizing Jaguar Health's Novel Crofelemer Powder for Oral Solution to Treat Two Pediatric Intestinal Failure Patients with Microvillus Inclusion Disease

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The two programs are being conducted under separate Single-Patient Investigational New Drug (sIND) applications in the United States

SAN FRANCISCO, CA / ACCESS Newswire / September 30, 2025 / Jaguar Health (NASDAQ:JAGX) today announced that Jaguar family company Napo Pharmaceuticals (Napo) is providing the company's novel crofelemer powder for oral solution for use in two expanded access programs, authorized by the U.S. Food and Drug Administration (FDA), to treat pediatric intestinal failure patients with microvillus inclusion disease (MVID).

"Napo is committed to providing the novel crofelemer formulation as an investigational drug as deemed medically necessary by the physician caregiver for these two patients, intended for mitigating the sequela from MVID disease progression," said Pravin Chaturvedi, PhD, Napo's and Jaguar's Chief Scientific Officer and Chair of the Scientific Advisory Board. "We wish both pediatric patients the best outcome and we are grateful to have this collaboration with the patients' physician."

Jaguar, through Jaguar family companies Napo and Napo Therapeutics, is currently supporting two independent proof-of-concept investigator-initiated trials (IIT), and conducting two placebo-controlled clinical studies, of crofelemer in patients with intestinal failure due to the ultrarare disease MVID and the rare disease indication short bowel syndrome with intestinal failure (SBS-IF) in the United States, European Union, and/or Middle East/North Africa regions under appropriate regulatory approvals in each of these geographies.

As announced, and as presented April 26, 2025 at the Annual ELITE PED-GI Congress, the initial proof-of-concept results of the ongoing IIT of a novel crofelemer powder formulation for oral solution in Abu Dhabi in the United Arab Emirates show that crofelemer reduced the required total parenteral nutrition (TPN) and supplementary intravenous fluids in the first participating MVID patient by up to 27% and in the first participating SBS-IF patient by up to 12.5%. An abstract describing the initial results of this trial has been accepted for presentation at the upcoming North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) Annual Meeting taking place November 5-8, 2025 in Chicago.

Additional proof-of-concept results from IITs of crofelemer for MVID and SBS-IF are expected later in 2025 and will provide additional preliminary data on the safety and potential effectiveness of crofelemer for these highly unmet clinical needs. Data from both above-referenced placebo-controlled clinical studies is expected in 2026.

In accordance with the guidelines of specific European Union countries, published data from clinical investigations could support reimbursed early patient access to crofelemer for these debilitating conditions in 2026 while the company pursues approval of crofelemer for MVID and SBS-IF from the European Medicines Agency (EMA) and the FDA. Participation in early access programs, which do not exist in the U.S., provides an opportunity for reimbursement while impacting the morbidity and high cost of care for these chronic unmet needs. Additionally, the company expects that if even just a very small number of MVID patients show benefit with crofelemer, this may potentially allow expedited regulatory pathways in the U.S. and other regions, including qualifying crofelemer for participation in PRIME, an EMA program providing enhanced interaction and early dialogue with drug developers of novel medicines targeting unmet medical needs, and in the FDA's Breakthrough Therapies program.

Patients with MVID and SBS-IF suffer from devastating diarrhea and dehydration caused by these debilitating, lifelong conditions. These patients are frequently on TPN for as long as 20 hours a day, seven days a week - and TPN carries a significant risk of morbidity, infections, metabolic complications, liver and kidney problems, and neurodevelopmental delay. There are no approved drug treatments for MVID, an ultrarare pediatric disease with an estimated prevalence of about 200 patients worldwide. Short bowel syndrome (SBS) affects approximately 10,000 to 20,000 people in the U.S., according to the Crohn's & Colitis Foundation, and it is estimated that the population of SBS patients in Europe is approximately the same size.

About Crofelemer
Crofelemer is a botanical (plant-based) drug extracted and purified from the red bark sap, also referred to as "dragon's blood," of the medicinal *Croton lechleri* tree in the Amazon Rainforest. Jaguar family company 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 (Napo) focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. 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 diseases.

For more information about:
Jaguar Health, visit https://jaguar.health
Napo Pharmaceuticals, visit www.napopharma.com
Napo Therapeutics, visit napotherapeutics.com

Visit the *Make Cancer Less Shitty* patient advocacy program on Bluesky, X, Facebook & Instagram

Forward-Looking Statements
Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that additional proof-of-concept results from IITs of crofelemer for MVID and SBS-IF will be available later in 2025 and will provide additional preliminary data on the safety and potential effectiveness of crofelemer for these highly unmet clinical needs, Jaguar's expectation that data from both above-referenced placebo-controlled clinical studies will be available in 2026, Jaguar's expectation that, in accordance with the guidelines of specific EU countries, published data from clinical investigations could support reimbursed early patient access to crofelemer for MVID and SBS-IF in 2026 while the company pursues approval of crofelemer for MVID and SBS-IF from the EMA and the FDA, and Jaguar's expectation that, if even just a very small number of MVID patients show benefit with crofelemer, this may potentially allow expedited regulatory pathways in the U.S. and other regions, including qualifying crofelemer for participation in the EMA's PRIME program and the FDA's Breakthrough Therapies program. 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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