Jaguar Health Announces Active Treatment Only Continuation of Pivotal Multicenter Clinical Trial in Pediatric Patients with Microvillus Inclusion Disease (MVID) to Support a New Drug Application (NDA) for Liquid Oral Crofelemer

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First MVID patient enters the active treatment only extension phase after completion of randomized double-blind crossover period to evaluate longer-term safety and efficacy with liquid oral crofelemer as adjunctive treatment for MVID, an ultrarare pediatric disease with a lethal natural history and no approved therapies, requiring lifelong parenteral support (PS)

SAN FRANCISCO, CA / ACCESS Newswire / May 19, 2026 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar) family company Napo Pharmaceuticals (Napo) announced that the first patient from the cohort of pediatric MVID patients in the pivotal MVID randomized double-blind crossover clinical trial has entered the active treatment only single-blind extension to evaluate the longer term safety and efficacy of crofelemer powder for oral solution as adjunctive treatment to parenteral support (PS) to support regulatory submissions for the drug to treat this serious unmet medical need. The trial is being conducted at multiple centers with appropriate regulatory approvals in the United States (US), European Union (EU), and United Arab Emirates (UAE).

MVID is an ultrarare congenital enteropathy that causes intestinal failure (IF) from early childhood. Patients with MVID require lifelong and life-sustaining PS, consisting of total parenteral nutrition (TPN) with or without supplemental intravenous fluids, to provide the life-sustaining nutrients, electrolytes, and fluids for survival. Most MVID patients require daily PS, sometimes for 20 hours or more per day. While crucial for growth and survival for these patients, PS is associated with significant comorbidities, such as liver and kidney toxicities, metabolic complications, infections, and neurodevelopmental delays. There are currently no approved drug treatments for MVID. Incidence of MVID is extremely rare with a lethal natural history. The company estimates that oral liquid crofelemer treatment is being used as adjunctive therapy with PS in up to 4% of the prevalent global MVID patient population.

"In MVID, the therapeutic goal is to evaluate crofelemer's oral treatment to reduce the increased needs of PS to support growth, hydration, electrolytes, and nutritional requirements. This single-blind extension phase is an important clinical milestone for our pivotal randomized double-blind crossover clinical trial of crofelemer in the MVID trial to support the development and regulatory approval of the drug, intended to provide the longer-term safety and efficacy of crofelemer in MVID patients," said Dr. Pravin Chaturvedi, Chair of Scientific Advisory Board and Chief Scientific Officer of Napo Pharmaceuticals and Jaguar Health. "The decision to allow pediatric MVID patients to continue into the active treatment only single-blind extension phase after completion of the randomized double-blind crossover period is made by an independent data monitoring committee, which evaluates the safety data in a blinded setting."

"This continuation of this pivotal clinical trial of crofelemer for treatment of MVID, which has a lethal natural history without life-sustaining parenteral support, and the burden on children and families is a key milestone for our development and regulatory submission plans," added Lisa Conte, President and CEO of Jaguar. "Our team continues to evaluate expedited regulatory pathways to support the approval of crofelemer as a potential first-in-class adjunctive therapy, if approved, to decrease PS requirements and improve the quality of lives of these MVID pediatric patients."

As previously announced, Jaguar family company Napo plans to complete this pivotal, adequate and well-controlled clinical trial for the ultrarare pediatric MVID to support an NDA filing in mid-2027, subject to study completion and regulatory alignment. The Company will also include data from two additional MVID patients being evaluated under expanded access and open-label study protocols due to the ultrarare incidence and prevalence of MVID. Data from these two patients will be presented at the upcoming European Society of Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) annual meeting in June 2026. Jaguar has received orphan drug designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for crofelemer for MVID treatment.

Jaguar's MVID program is a part of the company's adult and pediatric intestinal failure (IF) development programs. In addition to MVID, the novel crofelemer powder for oral solution is also being evaluated in a blinded trial in adult patients with short bowel syndrome with IF (SBS-IF).

About Crofelemer Powder for Oral Solution

Crofelemer powder for oral solution is a novel investigational oral formulation for treating the rare and orphan gastrointestinal disorders that cause intestinal failure, including MVID and SBS-IF. Crofelemer is a novel, plant-based antisecretory agent that acts locally in the gastrointestinal tract and helps normalize fluid and electrolyte balance by modulating chloride ion secretion. The formulation remains investigational and is currently not approved by FDA or EMA for MVID and SBS-IF.

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. Jaguar family companies Napo Pharmaceuticals Inc. (Napo) and Napo Therapeutics S.p.A. focus on the development and commercialization of novel crofelemer powder for oral solution for the treatment of rare and orphan gastrointestinal disorders with intestinal failure, including MVID and short bowel syndrome.

For more information about:

Jaguar Health, visit https://jaguar.health

Napo Pharmaceuticals, visit www.napopharma.com

Napo Therapeutics, visit napotherapeutics.com

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Certain statements in this press release constitute "forward-looking statements." 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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