Jaguar Health Announces Preliminary Discussion with FDA to Evaluate Breakthrough Therapy Designation for Crofelemer for Treatment of Microvillus Inclusion Disease (MVID)

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Pediatric patients with Intestinal Failure (IF) due to MVID, an ultrarare congenital disorder with lethal natural history, that has no available therapies and needs lifelong total Parenteral Support (PS), could benefit from expedited development of oral crofelemer via Breakthrough Therapy Designation

Crofelemer has demonstrated meaningful reductions in weekly PS needs in two pediatric MVID patients with initial results to be presented at ESPGHAN 2026

SAN FRANCISCO, CA / ACCESS Newswire / May 6, 2026 / Jaguar Health, Inc. (NASDAQ:JAGX) ("Jaguar") family company Napo Pharmaceuticals Inc., announced that the Company recently held a preliminary discussion with the Division of Gastroenterology at U.S. Food and Drug Administration (FDA) to evaluate the possibility of a Breakthrough Therapy Designation (BTD) for oral liquid crofelemer as an adjunctive therapy to PS for the treatment of pediatric patients with intestinal failure (IF) due to microvillus inclusion disease (MVID), an ultrarare congenital disorder with a lethal natural history requiring lifelong PS. Crofelemer has demonstrated preliminary clinical proof of concept (POC) in pediatric MVID patients in two open-label studies, with meaningful reductions in weekly PS requirements for the two MVID patients. Initial results for long-term evidence of efficacy and safety from the open label studies in pediatric MVID patients have been accepted for presentations at the upcoming 58th Annual ESPGHAN (European Society for Paediatric Gastroenterology Hepatology and Nutrition) Meeting in June, 2026. Crofelemer is also being evaluated in a pivotal randomized double-blind placebo-controlled clinical study in pediatric MVID subjects which has completed enrollment in this ongoing adequate and well-controlled trial.

*"*We are pleased with the initial clinical POC results for the safety and effectiveness of liquid oral crofelemer as adjunctive therapy to life sustaining PS in pediatric IF patients. Our objective is to evaluate expedited pathways to support availability of crofelemer for the serious unmet need of IF in patients with MVID. There are no available therapies for MVID other than lifelong PS which is inadequate and associated with profound comorbidities. Breakthrough therapy designation in the US and PRIME in the European Union are important potential regulatory pathways to expedite access. To the best of our knowledge, crofelemer is being used to treat approximately 4% of the estimated living pediatric MVID patients. Crofelemer has demonstrated meaningful reductions in PS needs for pediatric IF patients with MVID. Crofelemer has been well tolerated, and the pediatric MVID patients are gaining weight and height and demonstrating reductions in their daily and weekly needs for PS. Since PS is associated with significant comorbidities, reductions in PS needs are expected to improve clinical outcomes as well as quality of life measures," said Dr. Pravin Chaturvedi, Napo's Chief Scientific Officer and Chair of the company's Scientific Advisory Board.

Jaguar family company, Napo Pharmaceuticals, Inc., discussed the possibility of Breakthrough Therapy Designation for crofelemer for treatment of MVID as adjunctive therapy to lifelong PS with the FDA, given the preliminary clinical POC results in the open label studies. Breakthrough Therapy designation is an FDA program intended to expedite the development and review of drugs that are being developed to treat serious or life-threatening diseases or conditions where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on one or more clinically significant endpoints.

Jaguar and its family company Napo Pharmaceuticals have received orphan drug designations in the United States and European Union for crofelemer for both MVID and short bowel syndrome (SBS) with IF. The Company continues to advance its IF development programs, including ongoing work intended to support a potential future regulatory submission for crofelemer for MVID, subject to completion of the required clinical, regulatory, and manufacturing activities and further alignment with FDA.

"Engagement and regular communications with the FDA is a critical element of our effort to adopt the most efficient and expeditious pathway for crofelemer as a novel and first-in-class therapy for MVID as adjunctive therapy," Conte added. "We believe that oral crofelemer has the potential to modify the disease-progression of IF in MVID patients, and we intend to continue working with urgency to advance development and approval of crofelemer for this ultrarare pediatric patient population."

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 (IF), including MVID and Short Bowel Syndrome with IF (SBS-IF).

For more information about:

Jaguar Health, visit https://jaguar.health

Napo Pharmaceuticals, visit www.napopharma.com

Napo Therapeutics, visit napotherapeutics.com

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements related to crofelemer receiving Breakthrough Designation for MVID from the FDA. 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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