



Two Investigator-Initiated Responder Analysis Trials of Jaguar Health's Crofelemer Show Significant Positive Results for Chronic Refractory Diarrhea in IBS-D: Data Accepted for Presentation at American College of Gastroenterology 2024 Annual Meeting

August 1, 2024

It is estimated that 10-15% of people in the United States have IBS

SAN FRANCISCO, CA / ACCESSWIRE / August 1, 2024 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) ("Jaguar") family company [Napo Pharmaceuticals](#) ("Napo") today announced that the results of two independent investigator-initiated studies of crofelemer, Napo's novel, plant-based oral prescription drug, showed a benefit in patients with chronic refractory diarrhea and have been accepted for poster presentations at the [American College of Gastroenterology Annual Scientific Meeting](#), which takes place October 25-30, 2024 at the Pennsylvania Convention Center in Philadelphia.

"We are very excited that crofelemer continues to demonstrate clinical robustness in responder analysis trials for multiple gastroenterological conditions - including functional diarrhea and chronic idiopathic diarrhea. We are inspired to address the unmet needs, unmet symptom management, and patient comfort in these populations, which are often considered subgroups of diarrhea-predominant irritable bowel syndrome (IBS-D)," commented Lisa Conte, President and CEO of Jaguar. Crofelemer has been the subject of two previously presented Phase 2 trials in IBS-D.

Investigator-Initiated Study in Functional Diarrhea

Crofelemer significantly decreased stool consistency and abdominal pain without significant side effects, including constipation, in this small crossover study of 18 patients with functional diarrhea. The study showed that crofelemer may be a particularly useful option in those patients without a significant pain component to their symptoms, and it may be safe and effective in functional diarrhea, particularly given that its mechanism of action is not constipating. Larger trials are needed to more thoroughly assess safety and longer-term efficacy of crofelemer in functional diarrhea. Judy Nee, MD, was the principal investigator for the study. Dr. Nee is a gastroenterologist at Beth Israel Deaconess Medical Center and an assistant professor at Harvard Medical School. She serves as co-director of the GI Motility Lab at Beth Israel, and specializes in GI motility disorders and functional GI diseases such as IBS, chronic diarrhea, and constipation, as well as movement disorders of the esophagus.

Functional diarrhea, defined as chronic diarrhea for more than 6 months, is a common diagnosis without effective treatments. It is a functional gastrointestinal disorder, meaning it occurs without any other known signs of disease, injury, or structural problem. Patients participating in the study self-reported their daily overall stool consistency based on the Bristol Stool Form Scale (BSFS) and number of loose/watery bowel movements, together with their score for their worst abdominal pain, the score for their abdominal discomfort, and any bloating episodes. The study protocol defined a stool consistency endpoint responder as a patient having $\leq 50\%$ days with BSFS type > 5 (i.e., loose/watery stools), during the prior week compared to the last week of the baseline period.

Investigator-Initiated Study in Chronic Idiopathic Diarrhea

Chronic idiopathic diarrhea is a common complaint of patients presenting to family practitioners and internists, and is one of the most common reasons for referral to gastroenterologists. It is estimated that the prevalence of chronic idiopathic diarrhea in developed countries (including the U.S.) is approximately 3-5%. It has a significant negative effect on health-related quality of life and causes a high economic burden on patients and society.

"Despite significant advances in diagnostics, no organic etiology can be determined in a sizable proportion of patients suffering from chronic idiopathic diarrhea. Variable success for this condition has been observed with non-pharmacologic measures, over-the-counter therapies, and prescription agents. In this pilot study we found that crofelemer improved the symptoms of nearly 60% of patients with idiopathic chronic diarrhea. These results should prompt a larger evaluation of the effects of crofelemer in patients with chronic idiopathic diarrhea," said Brooks D. Cash, MD, AGAF, FACG, FASGE, the principal investigator for the study. Dr. Cash serves as Chief of the Gastroenterology, Hepatology, and Nutrition Division, and is a Professor of Medicine at the University of Texas Health Science Center at Houston.

The study prospectively recruited patients with chronic idiopathic diarrhea defined as 3 non-bloody loose/watery stools per day or more than 20 non-bloody loose/watery stools per week for ≥ 4 weeks, which corresponds to a stool consistency BSFS score of 6/7 for $> 50\%$ of their daily or weekly stools. Primary response was defined as a 50% decrease in mean BSFS 6/7 stool count per week by the end of week 4, and secondary response was defined as a decrease in average stool consistency by more than 2 levels in the BSFS from baseline to the end of treatment. Using this binary outcome, 58.8% of patients improved with crofelemer within the 4-week crofelemer treatment period.

"According to the American College of Gastroenterology, scientific tests show that about 10% to 15% of people in the United States have IBS, and almost twice as many women have IBS than men.¹ We look forward to continuing to investigate crofelemer for the treatment and management of chronic refractory diarrhea in patients with IBS-D," said Conte.

About Crofelemer

Crofelemer is the only oral prescription drug approved under FDA botanical guidance. It is plant-based, extracted and purified from the red bark sap of the *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 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 the *Make Cancer Less Shitty* patient advocacy program at makecancerlessshitty.com and on [X](#), [Facebook](#) & [Instagram](#)

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that crofelemer may be a particularly useful option in functional diarrhea patients without a significant pain component to their symptoms and that it may be safe and effective in functional diarrhea, and the expectation that crofelemer will continue to be investigated for the treatment and management of chronic refractory diarrhea in patients with IBS-D. 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.

¹ [ACG IBS FAQs](#)

CONTACT:

hello@jaguar.health

Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

press.releaseaccesswire.com