

Napo Pharmaceuticals, a Jaguar Health Family Company, Sponsoring Pediatric Gastroenterology Conference in Abu Dhabi and Panel Discussion About Microvillus Inclusion Disease (MVID)

April 29, 2024

Jaguar's novel plant-based prescription drug crofelemer has been granted Orphan Drug Designation by the FDA and the European Medicines Agency for both MVID and short bowel syndrome (SBS) with intestinal failure

Proof-of-concept studies of crofelemer for MVID and SBS planned for 2024

SAN FRANCISCO, CA / ACCESSWIRE / April 29, 2024 / Jaguar Health. Inc. (Nasdaq: JAGX) today announced that Jaguar family company Napo Pharmaceuticals (Napo) is a Bronze Sponsor of the 10th Annual Elite Ped-GI Congress, which takes place May 2-4, 2024 in Abu Dhabi in the United Arab Emirates (UAE). Additionally, at the conference Napo is sponsoring a panel discussion titled "Masterclass in Congenital Diarrhea" which will focus on microvillus inclusion disease (MVID), an ultra-rare congenital diarrheal disorder. Jaguar's novel plant-based prescription drug crofelemer has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for both MVID and short bowel syndrome (SBS) with intestinal failure.

"As previously announced, Jaguar, with strong leadership and participation from Jaguar family companies Napo Pharmaceuticals and Napo Therapeutics, is supporting investigator-initiated proof-of-concept studies of crofelemer for the rare disease indications of MVID and SBS with intestinal failure in the US, EU and Middle East/North Africa (MENA) regions, with results expected in 2024. Additionally, in August 2023 the FDA activated Napo Pharmaceuticals' Investigational New Drug (IND) application for a novel formulation of crofelemer for the treatment of MVID, which allows us to initiate our planned phase 2 trial of crofelemer for treatment of this indication in pediatric MVID patients," said Lisa Conte, Jaguar's president and CEO. "In accordance with the guidelines of specific EU countries, published data from clinical investigations in such rare diseases could support early patient access to crofelemer for these debilitating conditions in those countries."

MVID is a severe infantile disease characterized by diarrhea, malabsorption, and acid/base instability, requiring intensive parenteral support for nutritional and fluid management, and there are currently no approved drug treatments.

Dr. Mohamad Miqdady, a member of Napo's Scientific Advisory Board (SAB), will serve as the moderator of the Napo-sponsored panel discussion. The session panelists include Pravin Chaturvedi, PhD, who is Jaguar's Chief Scientific Officer and Chair of the Napo SAB, as well as Dr. Christos Tzivinikos and Dr. Antonella Diamanti, who are leading experts in the treatment of MVID patients in the UAE and Italy.

Dr. Miqdady is the Division Chief of the Pediatric Gastroenterology, Hepatology & Nutrition Division at Sheikh Khalifa Medical City, a flagship tertiary hospital in the UAE and the largest teaching medical center in Abu Dhabi. He is also an Adjunct Professor at Khalifa University's medical school in Abu Dhabi, and completed his Fellowship in Pediatric Gastroenterology at Baylor College of Medicine and Texas Children's Hospital in Houston.

Dr. Christos Tzivinikos is a Consultant Pediatric Gastroenterologist and Founder of the Pediatric GI Department at Al Jalila Children's Specialty Hospital in Dubai, and an Adjunct Clinical Assistant Professor at Mohammed Bin Rashid University of Medicine and Health Sciences in Dubai.

Dr. Diamanti is Head of the Artificial Nutrition Unit at <u>Bambino Gesù Children's Hospital</u> in Rome, Italy. She has served as Medical Director of the hospital's Gastroenterology Department since 2001.

Dr. Tzivinikos and Dr. Diamanti will be clinical investigators in Napo's planned phase 2 MVID study, titled *Evaluation of Safety, Tolerability and Efficacy of Crofelemer Following Multiple Ascending Doses of Crofelemer Powder for Oral Solution in Pediatric Participants with Microvillus Inclusion Disease (MVID).*

About the Elite Ped-GI Congress

This Elite Ped-GI Congress is designed to provide information about high level, clinically significant updates and comprehensive trends relevant to the practice of pediatric gastroenterological, nutrition and liver disorders. The annual event provides a venue for healthcare professionals to share their best practices, to network within groups of interest, and to create and strengthen clinical collaborations. Additional information about the Elite Ped-GI Congress can be viewed here on the event website.

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 innovative, patient-centric therapeutic solutions for essential supportive care and the management of neglected side effects across complicated disease states. Napo's goal is to redefine what is possible in supportive care, providing hope and improving outcomes for patients worldwide. Napo's crofelemer drug product candidate is the subject of the OnTarget study, a 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 from investigator-initiated and IND proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure will be available in 2024, the expectation that, in accordance with the guidelines of specific EU countries, published data from clinical investigations of crofelemer for MVID and SBS could support early patient access to crofelemer for these rare diseases in those countries, and the expectation that Jaguar will conduct a phase 2 clinical study of crofelemer for the treatment of 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 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.

Source: Jaguar Health, Inc.

Contact:

hello@jaquar.health

Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

press releaseaccesswire.com