Jaguar Health Completes Meeting with FDA for Advice on Development Pathways to Advance Ongoing Crofelemer Trial for Potential Approval for Treatment of Pediatric Indication Microvillus Inclusion Disease (MVID)

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Additional update: Results of ongoing investigator-initiated proof-of-concept trial in United Arab Emirates (UAE) demonstrate further reduction of total parenteral support (PS) (comprised of total parenteral nutrition and supplementary IV fluids) of approximately 37%

SAN FRANCISCO, CA, AL / ACCESS Newswire / October 6, 2025 / Jaguar Health, Inc. (NASDAQ:JAGX) (Jaguar) family company Napo Pharmaceuticals (Napo) today provided its assessment of the company's Type C Meeting with the U.S. Food and Drug Administration (FDA) on October 2, 2025 to seek their advice for efficient advancement of the company's clinical trial of its novel crofelemer powder formulation for oral solution for the treatment of microvillus inclusion disease (MVID), an ultrarare pediatric disorder. Members of Napo's Scientific Advisory Board, including a key opinion leader who is the principial investigator for the ongoing open-label investigator-initiated trial (IIT) in the UAE, along with its other advisors, participated in this meeting.

MVID is a devastating pediatric disorder, with an estimated worldwide prevalence of 100-200 patients, characterized by severe malabsorption that requires life-sustaining parenteral support to meet the nutritional, fluid and electrolyte requirements of the child, and for which there are currently no approved treatments. MVID has a lethal natural history along with significant co-morbidities.

"The company appreciates the collaborative and interactive discussion with the FDA. In our assessment, there may be potential opportunities to advance the development program for our ongoing MVID study to support approval of crofelemer for this indication. The company will continue its interactions with the FDA after making selected amendments to this clinical study. Upon agreement with the FDA, this small and adequately well-controlled study may allow a pathway to address critical unmet medical needs of MVID patients in a manner that supports evaluation of the clinical meaningfulness of disease progression-modification and potential translation for an approved label," said Pravin Chaturvedi, PhD, Napo's and Jaguar's Chief Scientific Officer and Chair of the Scientific Advisory Board.

"We are grateful to the FDA for their regulatory advice and support of our efforts for this ultrarare indication," said Lisa Conte, Jaguar's founder, president, and CEO. "Orphan drug designations have previously been received for crofelemer for MVID from the FDA and the European Medicines Agency (EMA). Pediatric patients from the U.S., European Union (EU), and the Middle East/North Africa (MENA) region are participating in our ongoing clinical trial of crofelemer for MVID. The company plans to pursue further discussions with regulatory agencies in the EU and MENA regions to bring crofelemer to MVID patients globally at the earliest possible time."

As stated above, the results of the ongoing investigator-initiated proof-of-concept trial in the UAE in a pediatric MVID patient demonstrate continued improvement of reduction of PS by 37% with a total parenteral nutrition (TPN) reduction of 30%. This improvement has been observed since reinitiation of crofelemer oral dosing following the protocol-mandated drug cessation at 12 weeks. The weekly reductions in PS and TPN of 37% and 30% are higher than the previously reported PS reduction of 27% at 12 weeks in this patient.

An abstract describing partial results of the IIT in the UAE 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.

In addition to supporting the IIT in the UAE and conducting the placebo-controlled clinical trial of crofelemer in pediatric MVID patients at sites in the U.S., EU, and Middle East under appropriate regulatory approvals in each of these geographies, the company is providing crofelemer powder for oral solution for use in two expanded access programs in the U.S., authorized by the FDA, to treat pediatric intestinal failure patients with MVID.

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 (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

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that there may be potential opportunities to advance the development program for the company's ongoing MVID study to support approval of crofelemer for the treatment of MVID, Jaguar's expectation that it will continue its interactions with the FDA after making selected amendments to the company's clinical MVID study, Jaguar's expectation that, upon agreement with the FDA, the company's study may allow a pathway to address critical unmet medical needs of MVID patients in a manner that supports evaluation of the clinical meaningfulness of disease progression-modification and potential translation for an approved label, Jaguar's expectation that the company will pursue further discussions with regulatory agencies in the EU and MENA regions to bring crofelemer to MVID patients globally at the earliest possible time, and Jaguar's expectation that an abstract describing partial results of the IIT in the UAE will be presented at the 2025 NASPGHAN Annual Meeting. 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 several 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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