



Jaguar Health's Executive VP Dr. Karen Brunke Joins BIO's Rare Disease and Orphan Drugs Committee

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Jaguar is supporting investigator-initiated proof-of-concept studies of crofelemer for the rare disease indications of short bowel syndrome and microvillus inclusion disease in the US, EU, and Middle East/North Africa regions, with results expected before the end of 2023 and in 2024

Dr. Brunke to present at the October 30-November 2, 2023 [World Orphan Drug Congress](#) in Barcelona and the November 6-8, 2023 [BIO-Europe®](#) conference in Munich

SAN FRANCISCO, CA / ACCESSWIRE / September 7, 2023 / [Jaguar Health, Inc.](#) (NASDAQ:JAGX), a commercial-stage pharmaceuticals company developing first-in-class plant-based gastrointestinal (GI) prescription medicines, today announced that Karen Brunke, PhD, the company's EVP of Corporate and Business Development, has become a member of the [Biotechnology Innovation Organization's](#) (BIO) Rare Disease and Orphan Drugs Committee.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

"I am very happy to have joined BIO's Rare Disease and Orphan Drugs Committee," said Dr. Brunke. "The committee provides an important forum for BIO members with a particular focus on rare diseases to discuss BIO's major advocacy issues and policies in relation to the development and marketing of orphan products. Jaguar has a core focus on two rare disease indications - short bowel syndrome (SBS) and microvillus inclusion disease (MVID) with intestinal failure - and I look forward to presenting at the October 30-November 2, 2023 [World Orphan Drug Congress](#) in Barcelona, Spain and the [BIO-Europe](#) conference in Munich, Germany to review the company's development efforts in this area."

BIO's Rare Disease and Orphan Drugs Committee is cross-functional, reviewing both FDA and development issues as well as market access and commercialization policies (including reimbursement). As such, the committee identifies and raises rare disease-specific issues to BIO's Health Care Reform and Reimbursement Committee. In 2020, the Rare Disease and Orphan Drug Committee prioritized developing consensus on, and advocating for, the Rare Pediatric Disease Priority Review Voucher program. The committee is currently working on developing a robust agenda for discussion with the FDA in a forthcoming meeting.

Jaguar is supporting investigator-initiated and investigator IND proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure in the US, European Union, and Middle East/North Africa (MENA) regions, with results expected before the end of 2023 and in 2024. In accordance with the guidelines of specific EU countries, published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID, potentially in 2024, for these debilitating conditions.

MVID is a catastrophic medical situation for pediatric patients, and there are currently no approved drug treatments. The company's Investigational New Drug application for crofelemer for the treatment of MVID was activated by the U.S. Food and Drug Administration (FDA) August 7, 2023.

Crofelemer has been granted Orphan Drug Designation (ODD) by the FDA and the European Medicines Agency for both MVID and SBS with intestinal failure. The ODD programs in the US and EU qualify sponsors to receive potential incentives to develop therapies for the diagnosis, prevention, or treatment of rare diseases or conditions.

About Crofelemer

Crofelemer is the only oral prescription drug approved by the FDA under 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, and bowel incontinence. Jaguar family company Napo Pharmaceuticals focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo Pharmaceuticals' crofelemer drug product candidate is the subject of the [OnTarget](#) study, an ongoing 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., is focused on developing novel prescription medicines derived from plants for mental health indications.

For more information about Jaguar Health, please visit <https://jaguar.health>. For more information about Napo Pharmaceuticals, visit www.napopharma.com. For more information about Napo Therapeutics, visit napotherapeutics.com. For more information about Magdalena Biosciences, visit magdalenabiosciences.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that Dr. Brunke will present at the 2023 World Orphan Drug Congress and the 2023 BIO-Europe conference, Jaguar's expectation that the results of investigator-initiated and investigator IND proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure will be available before the end of 2023 and in 2024, and Jaguar's expectation that published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID in European Union countries, potentially in 2024. 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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