Jaguar Health Enters Exclusive Crofelemer Revenue Sharing License and Commercialization Agreement with Quadri Pharmaceuticals Store for Rare Intestinal Failure Diseases in Middle East Markets

November 2, 2023

Quadri Pharma will cover 50% of the costs of development activity up to a capped dollar contribution

Jaguar to host virtual educational webinar on intestinal failure with leading gastroenterologists and nutrition experts November 8th from 1:00 PM to 2:30 PM EST; Click here to register for the webinar

SAN FRANCISCO, CA / ACCESSWIRE / November 2, 2023 / Napo Pharmaceuticals (Napo), a Jaguar Health, Inc. (NASDAQ:JAGX) family company, today announced that it has entered a revenue sharing license and commercialization agreement (the "Agreement") with Quadri Pharmaceuticals Store LLC (Quadri Pharma) that grants Quadri Pharma exclusive promotional, commercialization, and distribution rights for the rare disease indications of microvillus inclusion disease (MVID), other congenital diarrheal disorders, and short bowel syndrome (SBS) with intestinal failure for a powder formulation of crofelemer for oral solution in multiple Middle East countries, following regulatory approval to market crofelemer for these indications. In addition, the Agreement grants Quadri Pharma exclusive rights to distribute the powder formulation of crofelemer for the specified indications through Named Patient Programs in the specified Middle East countries following regulatory guidelines.

SBS can result from surgical resection of a portion of the small intestine, or from disease or injury, or be congenital. MVID is an ultra-rare congenital diarrheal disorder. An estimate of congenital birth defect rates shows a higher incidence of anomalies among live births in Arab countries compared to those in Europe, North America and Australia.[1] Many Arab countries display some of the highest rates of consanguineous marriages in the world ranging around 20-50% of all marriages, contributing to a higher-than-normal rate of congenital abnormalities.

"We are very happy to have entered this new collaboration with Quadri Pharma, which is distinct from the revenue sharing distribution and license agreement Napo and Quadri Pharma entered **in early 2022** that granted Quadri Pharma exclusive promotional, commercialization, and distribution rights to the tablet formulation of crofelemer in certain Middle East countries for specified human indications including HIV-related diarrhea and cancer therapy-related diarrhea (CTD), following regulatory approval," said Karen Brunke, PhD, Jaguar Health's Executive Vice President of Corporate and Business Development. "Under the terms of this new Agreement, Quadri Pharma will cover 50% of the costs of development activity in the specified territory for the powder formulation of crofelemer for the specified rare disease indications for three years, up to a certain total dollar amount. We look forward to continuing our close relationship with Quadri Pharma and their team of experienced professionals as we work together to expand access to crofelemer to intestinal failure patients in need in this region."

"We are very happy to enter into this new strategic relationship with Napo," said Dr. Hesham Elbakr, Chief Executive Officer of Quadri Pharma. "We expect crofelemer to be an important treatment option for patients suffering from the devastating rare diseases of SBS with intestinal failure and MVID in the Middle East countries specified in the Agreement. We have expertise in the distribution and marketing of prescription drugs throughout the Middle East, including the introduction and management of early access programs where that medicine does not have marketing approval and critically ill patients have very limited therapy options - such as requests related to Named Patient Programs, which provide access to individual patients ("named" patients) through physician requests."

Napo to Host Virtual Educational Webinar on Intestinal Failure with Leading Gastroenterologists and Nutrition Experts November 8, 2023 from 1:00 PM to 2:30 PM Eastern Standard Time

Participants in this virtual event, which will be moderated by Pravin Chaturvedi, PhD, Jaguar Health's Chief Scientific Officer and Chair of the Jaguar/Napo Scientific Advisory Board, will define intestinal failure, which is classified as a malabsorptive syndrome, discuss the current standards of care for SBS and MVID patients, including parenteral support, and address the major unmet need for treatment options for the debilitating, chronic, severe watery diarrhea that is associated with intestinal failure. Participants include these distinguished gastroenterologists and nutrition experts from the US, the Middle East and Europe:

- Professor Mohamad Miqdady, MD, Division Chief, Pediatric Gastroenterology, Hepatology & Nutrition Division, Sheikh Khalifa Medical City, Abu Dhabi, United Arab Emirates
- Professor Antonella Diamanti, MD, Head of Artificial Nutrition Unit, Bambino Gesù Pediatric Hospital, Rome, Italy
- Christos Tzivinikos, MD, DCH, FRCPCH, MSc, CEBP, Consultant Pediatric Gastroenterologist, Head of Pediatric Gastroenterology, Hepatology and Nutrition Department, Al Jalila Children's Specialty Hospital, Dubai, United Arab Emirates

- Lindsey Russell, MD, MSc, FRCPC, Department of Gastroenterology, Hepatology and Nutrition and the Digestive Diseases & Surgery Institute, Cleveland Clinic, Ohio
- Fabrizio Pasanisi, MD, PhD, Director of the Interuniversity Center for Studies and Research on Obesity (CISROD) and Professor of Internal Medicine, University of Naples Federico II, Naples, Italy
- Carol Wolin, MA, RDN, LD, Public Health Dietitian, Legacy Community Health, Houston, Texas

Webinar registration required via Zoom. To register, please click here or email Jaguar@TogoRun.com for more information.

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.

MVID patients commonly face intestinal failure - a catastrophic health situation that also often afflicts patients with SBS, a rare and complex condition characterized by diarrhea and/or severe malabsorption of fluids and nutrients. Crofelemer has been granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for both MVID and SBS. Jaguar is supporting investigator-initiated and investigator IND proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure in the US, EU, 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 European Union countries, published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or MVID for these debilitating conditions.

Napo's Investigational New Drug application for crofelemer for the treatment of MVID was activated by the FDA August 7, 2023.

Based in Abu Dhabi and Dubai in the UAE, Quadri Pharma provides services related to the registration, marketing, and distribution of pharmaceutical products in the MENA region in compliance with local and international regulatory standards.

About Crofelemer
Crofelemer is the only oral FDA-approved prescription drug under botanical guidance. It is plant-based, extracted and purified from the red bark sap of the *Croton lechleri* tree in the Amazon Rainforest. Napo Pharmaceuticals, a Jaguar family company, 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 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. 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/

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Forward-Looking Statements
Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that Jaguar Health will host a virtual educational webinar on intestinal failure on November 8, 2023, the expectation that crofelemer may be an important treatment option for patients suffering from SBS with intestinal failure and MVID in the Middle East countries specified in the Agreement, the expectation that results from proof-of-concept studies of crofelemer for MVID and SBS with intestinal failure may be available before the end of 2023 and in 2024, and the expectation that, in accordance with the guidelines of specific European Union countries, published data from such clinical investigations could support reimbursed early patient access to crofelemer for SBS or 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 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.

[1] Call for improved genetic services in Arab countries, Nature Middle East, Published online May 21, 2014

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SOURCE: Jaguar Health, Inc.

accesswire.com
https://www.accesswire.com/798653/jaguar-health-enters-exclusive-crofelemer-revenue-sharing-license-and-commercialization-agreement-with-quadri-pharmaceuticals-store-for-rare-intestinal-failure-diseases-in-middle-east-markets