



Jaguar Health Announces Completion of Key Milestone in Process of Establishing Indena S.p.A. as a Reliable Approved Crofelemer Manufacturer

January 25, 2023

Milestone supports the expansion of manufacturing volume required for potential additional indications for crofelemer, including cancer therapy-related diarrhea

Crofelemer API (active pharmaceutical ingredient) manufactured by Indena can now be used by Jaguar for development work

Patient enrollment expected to complete in Q2 2023 for company's pivotal Phase 3 [OnTarget](#) clinical trial of crofelemer for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy

SAN FRANCISCO, CA / ACCESSWIRE / January 25, 2023 / Jaguar Health, Inc. (NASDAQ:JAGX) today announced that the required procedure of registering the source of the active pharmaceutical ingredient (API) of crofelemer with the Agenzia Italiana Del Farmaco (AIFA), the Italian Medicines Agency, has been successfully completed. Resultingly, batches of crofelemer API manufactured by Milan, Italy-based Indena S.P.A. can now be used by Jaguar for further development work.

"We are very pleased about the completion of this key milestone in the ongoing process of establishing Indena as an additional approved crofelemer manufacturer as we work to support the increased crofelemer manufacturing demand expected upon potential FDA approval of crofelemer for new indications, including approval for cancer therapy-related diarrhea (CTD)," said David Sesin, Ph.D., Jaguar's chief manufacturing officer. "Jaguar is honored to have had a long-standing relationship with Indena, a pioneer and world-class leader in plant-based pharmaceutical manufacturing."

About Cancer Therapy-related Diarrhea

A significant proportion of patients undergoing cancer therapy experience diarrhea, and diarrhea has the potential to cause dehydration, potential infections, and non-adherence to treatment in this population. Novel "targeted cancer therapy" agents, such as epidermal growth factor receptor (EGFR) antibodies and tyrosine kinase inhibitors (TKIs), with or without cycle chemotherapy agents, may cause increased electrolyte and fluid content in the gut lumen, which results in passage of loose/watery stools (i.e., diarrhea). Diarrhea has been reported as one of the most common side effects of TKIs and may result in cancer therapy drug holidays or reductions from therapeutic dose, potentially impacting patient outcome. Diarrhea is also a common side effect of some approved CDK 4/6 inhibitors.

About Indena S.p.A.

Indena is the leading company dedicated to the identification, development and production of high-quality active principles derived from plants, for use in the pharmaceutical and health food industries. Backed by a century of botanical experience, the company owns 100 patent families, has published more than 1,000 scientific studies, and co-operates with the world's most prestigious universities and private research institutions. Indena employs over 900 staff, investing a significant amount of its annual turnover in research, making this activity the key to its success. Headquartered in Milan, Italy, Indena has 4 production sites and 5 international branches throughout the world and manages sales in more than 80 countries. The company's experts communicate and interact constantly with the major international regulatory authorities and cooperate on the update of all the main pharmacopoeias. Learn more at indena.com

About Jaguar Health, Napo Pharmaceuticals, Napo Therapeutics & Jaguar Animal Health

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, plant-based, non-opioid, and sustainably derived prescription medicines for people and animals with GI distress, including chronic, debilitating diarrhea. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human pharmaceuticals from plants harvested responsibly from rainforest areas. Our crofelemer drug product candidate is the subject of the [OnTarget](#) study, an ongoing pivotal Phase 3 clinical trial for prophylaxis of diarrhea in adult cancer patients receiving targeted therapy. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A. (f/k/a Napo EU S.p.A.), an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe. Jaguar Animal Health is a tradename of Jaguar Health.

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.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the potential for FDA approval of

crofelemer for new indications, including CTD. 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.

Contact:

Peter Hodge
Jaguar Health, Inc.
phodge@jaguar.health

Jaguar-JAGX

SOURCE: Jaguar Health, Inc.

accesswire.com

<https://www.accesswire.com/736627/Jaguar-Health-Announces-Completion-of-Key-Milestone-in-Process-of-Establishing-Indena-SpA-as-a-Reliable-Approved-Crofelemer-Manufacturer>