



Jaguar Health's CDMO Improves Manufacturing Processes to Support the Expanded Crofelemer Manufacturing Volume Expected to be Required for Potential Expanded Indications, Including a Potential Indication for Cancer Therapy-related Diarrhea

August 2, 2019

SAN FRANCISCO, CA / ACCESSWIRE / August 2, 2019 /Jaguar Health, Inc. (NASDAQ:JAGX) (“Jaguar” or the “Company”), a commercial stage pharmaceutical company focused on developing novel, sustainably derived gastrointestinal products on a global basis, announced today that Indena S.p.A., one of the two contract manufacturers of the active pharmaceutical ingredient (API) in crofelemer, has successfully developed and implemented an improved crofelemer manufacturing process, effectively increasing yield and realizing reduced cost through increased manufacturing efficiencies while retaining the same phytochemical profile without compromising product quality, safety, purity and efficacy. The modified process allows Jaguar’s wholly-owned human-health subsidiary, Napo Pharmaceuticals, Inc., to support the increased crofelemer manufacturing demand expected if crofelemer receives FDA approval for new indications, including approval for the symptomatic relief of cancer therapy-related diarrhea (CTD).

As previously announced, the potential CTD indication is the primary focus of the Company’s ongoing crofelemer-related development efforts. A significant proportion of patients undergoing cancer therapy experience diarrhea. Novel targeted cancer therapy agents, such as epidermal growth factor receptor antibodies and TKIs, with or without cycle chemotherapy agents, may activate intestinal chloride secretory pathways, leading to increased chloride secretion into the gut lumen, coupled with significant loss of water, that would result in secretory diarrhea.

“We’re very pleased that Indena has completed process development activities at the lab scale and pilot scale and that they have the equipment and in-depth expertise in place to transfer the process into their industrial facility,” David Sestin, Ph.D., Jaguar’s chief manufacturing officer, commented. “The improved process supports our goal of increasing product yield, lowering cost of goods, and securing manufacturing capacity to support future growth.”

Headquartered in Milan, Italy, Indena, with almost 100 year of experience in the sector, is a leading CDMO provider, with a focus on complex small molecules and natural derivatives.

About Crofelemer

Crofelemer is a botanical (plant-based) drug extracted and purified from the red bark sap of the medicinal Croton lechleri tree in the Amazon rainforest. Napo has established a sustainable harvesting program for crofelemer to ensure a high degree of quality and ecological integrity.

About Jaguar Health, Inc.

Jaguar Health, Inc. is a commercial stage pharmaceuticals company focused on developing novel, sustainably derived gastrointestinal products on a global basis. Our wholly-owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary human gastrointestinal pharmaceuticals for the global marketplace from plants used traditionally in rainforest areas.

For more information about Jaguar, please visit jaguar.health. For more information about Napo, visit napopharma.com.

About Indena S.p.A.

Indena is a leading CDMO provider, specialized in the research, development and production of complex active principles, with a unique expertise for natural derivatives, for use in the pharmaceutical, health-food and personal care industries. Headquartered in Milan, Italy, Indena has around 800 employees (10% of them dedicated to full-time research) and has cultivation, manufacturing, and sales in more than 70 countries throughout the world.

Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements.” These include statements regarding the possible approval by FDA of crofelemer for new indications, including a possible indication for CTD, and the expectation that expanded crofelemer manufacturing volume will be required if crofelemer receives FDA approval for a new indication such as 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)

<https://www.accesswire.com/554349/Jaguar-Healths-CDMO-Improves-Manufacturing-Processes-to-Support-the-Expanded-Crofelemer-Manufacturing-Volume-Expected-to-be-Required-for-Potential-Expanded-Indications-Including-a-Potential-Indication-for-Cancer-Therapy-related-Diarrhea>