



Jaguar Health Announces Receipt by Napo Therapeutics of Small and Medium Enterprise (SME) Designation from the European Medicines Agency

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SME status is an important designation for Italy-based Napo Therapeutics' rare/orphan disease business model

SAN FRANCISCO, CA and MILAN, ITALY / ACCESSWIRE / February 15, 2022 / Jaguar Health (**NASDAQ:JAGX**) and Napo Therapeutics S.p.A., an Italian corporation established by Jaguar Health in Milan, Italy, today announced that Napo Therapeutics has been granted Small and Medium Enterprise (SME) designation by the European Medicines Agency (EMA).

"We are very pleased to have received SME designation, which allows us to benefit from financial incentives and support from the EMA as we aim to provide access to crofelemer in Europe for significant rare/orphan diseases," said Massimo Mineo, General Manager of Napo Therapeutics.

The SME designation was established by the EMA to promote innovation and the development of new medicinal products by smaller companies.

"Companies with SME status have displayed a high success rate for marketing authorization applications in the European Union - reaching 89% in 2020 - and receive financial advantages on all associated regulatory fees and activities," said Annabella Amatulli, Chief Regulatory Officer of Napo Therapeutics. "Companies with SME status developed nearly 20% of all human medicines recommended for authorization by the EMA in 2020, and half of these medicines target a rare disease."

SME status also allows companies to receive special regulatory benefits, such as the ability to engage in an early dialogue with a dedicated, multidisciplinary EMA team to discuss regulatory strategy, receipt of guidance on clinical data publication, and discuss eligibility for the EMA's programs (such as the PRIME program) and other dedicated initiatives.¹

About Jaguar Health, Inc., Jaguar Animal Health, Napo Pharmaceuticals, Inc. & Napo Therapeutics S.p.A.

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, specifically chronic, debilitating diarrhea. Jaguar Animal Health is a tradename of Jaguar Health. Jaguar Health's wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals from plants harvested responsibly from rainforest areas. Jaguar Health is the majority shareholder of Napo Therapeutics S.p.A., an Italian corporation established by Jaguar Health in Milan, Italy in 2021 that focuses on expanding crofelemer access in Europe.

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 www.napotherapeutics.com.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." 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 Health 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 Health's control. Except as required by applicable law, Jaguar Health 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 <https://www.ema.europa.eu/en/human-regulatory/overview/support-smes>

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