



## Jaguar Health's Italian Subsidiary Napo EU Appoints Annabella Amatulli Chief Regulatory Officer

November 8, 2021

**SAN FRANCISCO, CA / ACCESSWIRE / November 8, 2021 /** Jaguar Health, Inc. (NASDAQ:JAGX) today announced the appointment by Napo EU S.p.A., the company's Italian subsidiary, of Annabella Amatulli as chief regulatory officer. A recognized expert in global regulatory affairs, Ms. Amatulli will be responsible for both high-level strategic planning and hands-on support for Napo EU's development programs and licensed products from a regulatory perspective and serve as the primary liaison between Napo EU and European health authorities.

"We consider ourselves very fortunate to have identified Annabella for this very important role at Napo EU, and even more fortunate that she has joined as the first member of the Napo EU team," stated Lisa Conte, Jaguar's president and CEO and Napo EU board member. "She brings vast experience to the team, having worked in regulatory affairs throughout Europe and in other key regions of the world."

Ms. Amatulli previously served as a Global Regulatory Affairs Director at Dompé, an Italian bio-pharmaceutical company that markets 50 million medication packages in roughly 40 countries around the world. Ms. Amatulli also spent more than six years in regulatory affairs with the Janssen Pharmaceutical Companies of Johnson & Johnson. Her recent track record includes approval of the Oxervate® (rhNGF) dossier in the US, China, EU and four other countries for the treatment of a rare disease of the eye; discussion with FDA, EMA and ANVISA about the development plan of 2 investigational products for COVID-19 treatment; the preparation and submission of three Investigational New Drug Applications (INDs) for different therapeutic areas (diabetes, oncology and ophtha); the development of a Global Early Access Program (Managed Access Program and Named-Patient Program); and the set-up of local affiliates in EU-5 countries (France, Germany, Italy, Spain and the United Kingdom), the US, and China from a regulatory standpoint. Ms. Amatulli holds a BS degree in Pharmaceutical Biotechnology from the Università Degli Studi Di Milano, and a master's degree in Molecular Biology from the Università Degli Studi Milano-Bicocca.

"I am thrilled to join Napo EU to apply my experience in driving regulatory strategy to give not only a hope to patients but an approved treatment for a rare and serious disease. Our goal here in Napo EU is working to advance promising treatments for patients to significantly improve their quality of life," said Ms. Amatulli.

Napo EU was formed with the mission to expand access to crofelemer to Europe to address significant unmet gastrointestinal medical needs in the region. Napo EU's initial focus is on pursuing the accelerated conditional marketing authorization pathway from the European Medicines Agency (EMA) for crofelemer for an important orphan-designated disease: short bowel syndrome with intestinal failure (SBS-IF).

Napo EU has hired a 20+ year veteran of Europe's pharmaceutical industry to serve as general manager. This individual will join Napo EU on November 15, 2021 and be responsible and accountable for the strategy, planning and implementation of all commercial and operational activities within Europe, with success defined by bringing crofelemer to market for target indications, beginning with SBS-IF.

The process is currently underway to identify candidates for the Napo EU chief medical officer role. Napo EU's CMO will be responsible for leading and directing all Napo EU clinical programs intended to support marketing authorization in Europe for crofelemer target indications.

### **About Jaguar Health, Inc., Napo Pharmaceuticals, Inc. & Napo EU 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 GI distress, specifically chronic, debilitating diarrhea. Our wholly owned subsidiary, Napo Pharmaceuticals, Inc., focuses on developing and commercializing proprietary plant-based human gastrointestinal pharmaceuticals from plants harvested responsibly from rainforest areas. Our Mytesi® (crofelemer) product is approved by the U.S. FDA for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral therapy and the only oral plant-based prescription medicine approved under FDA Botanical Guidance. Crofelemer 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. Napo EU S.p.A., the substantially owned Italian subsidiary of Napo Pharmaceuticals, focuses on expanding crofelemer access in Europe.

For more information about Jaguar, please visit <https://jaguar.health>. For more information about Napo Pharmaceuticals, visit [www.napopharma.com](http://www.napopharma.com). For more information about Napo EU, visit [www.napoeu.com](http://www.napoeu.com).

### **About Mytesi®**

Mytesi® (crofelemer delayed release tablets) is an antidiarrheal indicated for the symptomatic relief of noninfectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy (ART). Mytesi is not indicated for the treatment of infectious diarrhea. Rule out infectious etiologies of diarrhea before starting Mytesi. If infectious etiologies are not considered, there is a risk that patients with infectious etiologies will not receive the appropriate therapy and their disease may worsen. In clinical studies, the most common adverse reactions occurring at a rate greater than placebo were upper

respiratory tract infection (5.7%), bronchitis (3.9%), cough (3.5%), flatulence (3.1%), and increased bilirubin (3.1%).

More information and complete Prescribing Information are available at [Mytesi.com](http://Mytesi.com)

#### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that Napo EU may receive approval for a drug to treat a rare and serious disease. 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.

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