



## **Jaguar Health Licenses FDA-Approved Oral Mucositis Product for U.S. Market, Initiating Commercial Footprint in its Core Focus Area of Cancer Supportive Care**

April 16, 2024

***Jaguar planning to begin commercial launch in Q3 2024 for Gelclair<sup>®</sup>, the company's third prescription product***

***Oral mucositis, also called "chemo mouth," has emerged as the most significant adverse event in oncology according to a National Comprehensive Cancer Network task force***

**SAN FRANCISCO, CA / ACCESSWIRE / April 16, 2024 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#)** ("Jaguar") today announced that it has signed an exclusive 5-year in-license agreement with United Kingdom-based Venture Life Group PLC ("Venture Life"), an international consumer health company focused on the global self-care market, for Venture Life's FDA-approved oral mucositis prescription product, Gelclair, for the U.S. market.

"We are very happy to have executed the in-license agreement for Gelclair - and thus to have initiated Jaguar's commercial footprint in our core focus area of cancer supportive care," said Lisa Conte, Jaguar's president and CEO. "Oral mucositis is among the most common, painful, and debilitating cancer treatment-related side effects. Gelclair is a protective gel with a mechanical action indicated for the management of pain and relief of pain by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis. Unlike other products for oral mucositis, it is not a numbing agent and does not sting the mouth."

Oral mucositis, also called "chemo mouth," has emerged as the most significant adverse event in oncology according to a National Comprehensive Cancer Network (NCCN) task force.<sup>1</sup> Up to 40% of all patients treated with chemotherapy develop oral mucositis, and this percentage rises to approximately 90% for patients with head and neck cancers treated with chemotherapy and radiotherapy. Of the latter, 19% may end up being hospitalized, experiencing a delay in antineoplastic treatment for high-grade mucositis management, resulting in a reduction of the quality of life, a worse prognosis and an increase in patient management costs.<sup>2</sup>

"A key attribute in the management of head and neck cancer patients with Gelclair is, in my experience, to delay the onset which may decrease the severity of oral mucositis, allowing the patients to continue meeting their nutritional needs without having to go on a feeding tube, supporting their ability to withstand their 6 weeks of radiation therapy without having to go to lower doses or treatment interruptions, and to avoid the need for heavy prescription meds for oral mucositis-related pain," said Maged Ghaly, MD, a radiation oncologist at Northwell Health Cancer Institute, Monter Cancer Center.

"Gelclair is an FDA-approved prescription product and can be commercialized without any clinical development costs for Jaguar," added Conte. "We are expanding our footprint beyond HIV-related supportive care to include cancer-related supportive care, and the in-license of Gelclair is a first building block while we await the forthcoming results from our pivotal Phase 3 [OnTarget](#) trial of crofelemer for cancer therapy-related diarrhea, an indication we also refer to as chemotherapy-induced overactive bowel (CIOB) - which includes symptoms such as unpredictable and/or chronic debilitating diarrhea and GI urgency. We live in the age targeted therapies, and thanks to these amazing drugs cancer patients are living longer - 5, 10, 20 years. Targeted therapies often lead to more severe side effects, however, and patients want to live, not just survive."



Oral mucositis can negatively affect diet, nutrition, oral hygiene, and quality of life.<sup>3</sup> Its adverse physical, social and psychological impacts on patients are manifest and include the need for total parenteral nutrition, higher risk of systemic infections, increased use of antifungals and opioid analgesics, increased hospitalizations with longer hospital stays, social isolation and depression due to the inability to talk and eat, subsequent dose reductions, treatment interruptions and discontinuations, and as a corollary to dose reductions and treatment interruptions/discontinuations, diminished anti-tumor responses and shorter survival.<sup>1</sup>

The economic consequences are far from trivial, with the incremental cost of oral mucositis exceeding \$17,000 for patients with head and neck cancer.<sup>4</sup>

Gelclair is a clinically proven, convenient, and easy to use gel that provides rapid and long-lasting pain relief and improves the ability of oral mucositis patients to eat, drink, swallow, speak and sleep. Gelclair also reduces the need to use parenteral feeding or opiate analgesics.

#### **About Gelclair®**

#### **INDICATIONS**

GELCLAIR® has a mechanical action indicated for the management of pain and relief of pain by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiation therapy), irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, or disease. Also, indicated for diffuse aphthous ulcers.

#### **IMPORTANT SAFETY INFORMATION**

- Do not use GELCLAIR if there is a known or suspected hypersensitivity to any of its ingredients.
- No adverse effects have been reported in clinical trials, although postmarketing reports have included infrequent complaints of burning sensation in the mouth.
- If GELCLAIR is swallowed accidentally, no adverse effects are anticipated.
- If no improvement is seen within 7 days, a physician should be consulted.

You are encouraged to report negative side effects of prescription medical products to the FDA.

Visit [www.fda.gov/safety/medwatch](http://www.fda.gov/safety/medwatch), call 1-855-273-0468 or fill-in the form at this [link](#).

**Please see full Prescribing Information at:**

[https://gelclair.com/assets/Gelclair\\_PI\\_Decemeber\\_2021.pdf](https://gelclair.com/assets/Gelclair_PI_Decemeber_2021.pdf)

### **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, a 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](http://www.napopharma.com)

Napo Therapeutics, visit [napotherapeutics.com](http://napotherapeutics.com)

Magdalena Biosciences, visit [magdalenabiosciences.com](http://magdalenabiosciences.com)

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### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that top line results from the OnTarget study are forthcoming. 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.

<sup>1</sup> Oronsky B, et al. *Transl Oncol*. 2018;11(3):771-778.

<sup>2</sup> Pulito C, Cristaudo A, Porta C, Zapperi S, Blandino G, Morrone A, Strano S. Oral mucositis: the hidden side of cancer therapy. *J Exp Clin Cancer Res*. 2020 Oct 7;39(1):210. doi: 10.1186/s13046-020-01715-7. PMID: 33028357; PMCID: PMC7542970

<sup>3</sup> Jensen SB, Peterson DE. *J Oral Pathol Med*. 2014;43(2):81-90.

<sup>4</sup> Nonzee NJ, et al. *Cancer*. 2008;113(6):1446-1452.

Source: Jaguar Health, Inc.

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