



**Jaguar Health to Initiate Commercial Footprint in Cancer Supportive Care at American Society of Clinical Oncology (ASCO) Annual Meeting with Exhibit Booth for FDA-Approved Gelclair Oral Mucositis Product**

May 23, 2024

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

Top line results imminent for company's phase 3 [OnTarget](#) trial of crotetlemer for preventative treatment of cancer therapy-related diarrhea

18 million people in U.S. are living with a cancer diagnosis and more than 2 million people in U.S. are expected to be diagnosed with cancer in 2024

SAN FRANCISCO, CA / ACCESSWIRE / May 23, 2024 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) ("Jaguar") today announced that it is initiating the company's commercial footprint in its core focus area of cancer supportive care at the May 31 - June 4 [American Society of Clinical Oncology \(ASCO\) Annual Meeting](#) with a [Napo Pharmaceuticals \(Napo\)](#) exhibit booth for Gelclair®, the FDA-approved oral mucositis prescription product Jaguar in-licensed last month for the U.S. market. Napo is a Jaguar family company. Jaguar plans to begin the commercial launch in Q3 2024 for Gelclair.

"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," said Lisa Conte, Jaguar's president and CEO.

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>



Oral mucositis can negatively affect diet, nutrition, oral hygiene, as well as 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>

"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, Montefiore Cancer Center.

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.

"We look forward to driving awareness among oncologists at the ASCO Annual Meeting about Gelclair and Jaguar's expanding focus on cancer supportive care," said Conte. "The depth of our commitment to people living with a cancer diagnosis is further exemplified by the 5-year commitment we've made to clinically study prophylaxis of cancer therapy-related diarrhea with our phase 3 [OnTarget](#) trial - specifically focusing on the more than 24 targeted cancer agents that have an incidence of greater than 50% diarrhea. Top line results from this pivotal study are imminent."

**About the Pivotal Phase 3 OnTarget Trial**

OnTarget is a first-of-its-kind, 24-week (two 12-week stages) clinical trial with a primary endpoint based on patient-reported outcomes that address the highly neglected and unmet burden of cancer therapy-related diarrhea, an indication Jaguar also refers to as preventive treatment of chemotherapy-induced overactive bowel (CIOB) - which includes symptoms such as chronic and/or episodic debilitating diarrhea (loose and/or watery stools), urgency, bowel incontinence and abdominal pain and discomfort.

Diarrhea is a common side effect of targeted therapies and new treatments are needed. Up to 95% of patients on tyrosine kinase inhibitors (TKIs) suffer from diarrhea, depending on the TKI used.<sup>5</sup> The OnTarget study is testing whether the company's plant-based prescription drug crotetlemer (versus placebo) can prevent (or substantially reduce) diarrhea and other symptoms of CIOB when any one of the selected 24 different targeted therapies (that are associated with diarrhea in at least 50% of patients) is initiated. More than 2 million people are expected to be diagnosed with cancer in 2024 in the U.S., according to the American Cancer Society.<sup>6</sup> Cancer patients with diarrhea have been shown to be 40% more likely to discontinue their targeted therapy.<sup>7</sup>

#### About ASCO

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO)<sup>®</sup> is committed to the principle that knowledge conquers cancer. Together with the Association for Clinical Oncology, ASCO represents nearly 50,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of high quality, equitable patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. Conquer Cancer, the ASCO Foundation, supports ASCO by funding groundbreaking research and education across cancer's full continuum. Learn more at [www.asco.org](http://www.asco.org).

#### About GELclair<sup>®</sup>

**INDICATIONS**  
GELclair<sup>®</sup> 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\\_December\\_2021.pdf](https://gelclair.com/assets/Gelclair_PI_December_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 [DuoTaggart](#) 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 trademark. Magdalena Biosciences, a joint venture formed by Jaguar and Filament Health Corp, that emerged from Jaguar's [Enbaugus 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)

Visit Jaguar on LinkedIn: <https://www.linkedin.com/company/jaguar-health>

Visit Jaguar on X: [https://twitter.com/Jaguar\\_Health](https://twitter.com/Jaguar_Health)

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#### Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding the expectation that Napo will exhibit at the 2024 ASCO Annual Meeting, and Jaguar's expectation that the top line results from the OnTarget trial are imminent. 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, Zappet S, Blandino G, Morone 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.

<sup>5</sup> Moschen AR, Sammy Y, Marjénberg Z, Hepfinstall AB, Poolley N, Marczevska AM. The Underestimated and Overlooked Burden of Diarrhea and Constipation in Cancer Patients. *Curr Oncol Rep*. 2022;24(7):861-874. doi:10.1007/s11912-022-01267-3

<sup>6</sup> <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2024/2024-cancer-facts-and-figures-acp.pdf>

<sup>7</sup> Pablo C. Okhuysen, M.D., The impact of cancer-related diarrhea on changes in cancer therapy patterns: Real world evidence

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**SOURCE:** Jaguar Health, Inc.

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Company Update