



Jaguar Health Launches FDA-Approved Oral Mucositis Prescription Product Gelclair in the U.S.

October 16, 2024

Gelclair® is the company's third commercialized prescription product

Oral mucositis, also called "chemo mouth," a painful inflammation of the mouth's mucous membranes, has emerged as the most significant adverse event in oncology according to a National Comprehensive Cancer Network task force

Severe mucositis/pharyngitis occurred in 70% of head and neck cancer patients in third-party study

SAN FRANCISCO, CA / ACCESSWIRE / October 16, 2024 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) ("Jaguar") today announced that Jaguar family company [Napo Pharmaceuticals](#) ("Napo") has initiated the commercial launch of the FDA-approved oral mucositis prescription product Gelclair in the U.S.

"Cancer is chaotic, because patients feel a loss of control - over their life, their treatment, and their supportive care needs," said Catherine Collis, Jaguar's Senior Vice President of Growth Strategy. "Jaguar's mission is to change patients' lives for the better, especially in the area of supportive care for complex disease states like cancer. We are thrilled to have begun our commercial launch of Gelclair. Oral mucositis is undertreated and underappreciated. We believe we can help cancer patients by giving them a supportive care product for oral mucositis that provides soothing, quick, and lasting pain relief without stinging, drying or burning."

"We are very happy to have initiated the commercial launch for Gelclair - our third commercialized prescription product. This important milestone initiates 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 gel with a mechanical action indicated for the management of pain and relief of pain by adhering to the mucosal surface of the mouth. It coats and protects the oral mucosa, which supports healing. Gelclair is convenient and easy to use, provides rapid and long-lasting pain relief, and improves the ability of oral mucositis patients to eat, drink, and swallow. Unlike other products for oral mucositis, it is not a numbing agent and does not sting the mouth."

"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.

Napo's core target audiences for the Gelclair launch are patients with head and neck cancer and oncology-focused health care practitioners. Head and neck cancers account for nearly 4 percent of all cancers in the United States, according to the National Cancer Institute (NCI).¹ Counting cancers of the oral cavity, pharynx, and larynx, the NCI estimates that about 71,110 cases will occur in the U.S. in 2024.²

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.³ 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.⁴ 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.⁴ Oral mucositis impacts a patient's ability to swallow, speak, eat, and drink - and may lead to cancer treatment discontinuation.⁵ It is estimated that at least 11% of head and neck cancer patients experience cancer treatment interruption due to oral mucositis.⁶

"Those of us working in the oncology field know the impact that side effect-related delays or cessation of cancer treatment can have on overall survival and on the efficacy of treatment," Collis said. "Of patients with head and neck cancers treated with chemotherapy and radiotherapy who develop oral mucositis, half of the cases are typically considered severe - meaning oral mucositis of grade 3 or 4, which typically puts a patient in the hospital requiring parenteral nutrition and iv hydration, and the morbidity and expense associated with that."

"We've dedicated a great deal of effort to ensuring that our commercial launch plan for Gelclair is executed with sharp strategic focus. Given Jaguar's core focus on cancer supportive care, we've developed a dedicated team of educational, promotional and sales representatives with extensive experience in this area. This positions us well as we anticipate future new products in the cancer supportive care space," added Collis.

As part of the ongoing Gelclair launch, Napo plans to exhibit at several key oncology conferences in the coming months, and there will also be a strong digital marketing component to the launch, targeting health care providers and providing information and education for patients to self-advocate.

Tom Barnes, a cancer patient and a paid consultant to Napo, commented: "I would say that the BIGGEST impact oral mucositis has had on my treatment plan has been a delay in me getting comfortable with being able to eat solid foods again. Even though the mucositis is relatively confined to the interior of my mouth, the sense of it being there also contributes towards that sense of body image being damaged."



Oral mucositis can negatively affect diet, nutrition, oral hygiene, and quality of life.⁷ 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.⁸

The economic consequences are far from trivial. In a third-party study, severe mucositis/pharyngitis occurred in 70.1% of 99 patients with head and neck cancer, with the incremental cost of oral mucositis exceeding \$17,244 for these patients.⁹

For more information about Gelclair, visit www.gelclair.com.

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 (Napo) focuses on developing and commercializing human prescription pharmaceuticals for essential supportive care and management of neglected gastrointestinal symptoms across multiple complicated disease states. Napo's crofelemer is FDA-approved under the brand name Mytesi[®] for the symptomatic relief of noninfectious diarrhea in adults with HIV/AIDS on antiretroviral 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

Napo Therapeutics, visit napotherapeutics.com

Magdalena Biosciences, visit magdalenabiosciences.com

Visit the *Make Cancer Less Shitty* patient advocacy program at makecancerlessshitty.com and on [X](#), [Facebook](#) & [Instagram](#)

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, 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

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements." These include statements regarding Jaguar's expectation that it will have additional products for the cancer supportive care space in the future, and Jaguar's expectation that, as part of the ongoing Gelclair launch, Napo will exhibit at several oncology conferences in the coming months and there will also be a strong digital marketing component to the launch. 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 several 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.

¹ <https://www.cancer.gov/types/head-and-neck/head-neck-fact-sheet>

² <https://www.aacr.org/patients-caregivers/awareness-months/head-and-neck-cancer-awareness-month/>

³ NCCN Task Force Report: Prevention and Management of Mucositis in Cancer Care. Journal of the National Comprehensive Cancer Network J Natl Compr Canc Netw, 6(S1), S-1-S-21. <https://doi.org/10.6004/jnccn.2008.2001>

⁴ 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

⁵ Vera-Llonch M, Oster G, Hagiwara M, Sonis S. Oral mucositis in patients undergoing radiation treatment for head and neck carcinoma. Cancer. 2006;106(2):329-336. doi:10.1002/cncr.21622.

⁶ Trotti A, et al. Mucositis incidence, severity and associated outcomes in patients with head and neck cancer receiving radiotherapy with or without chemotherapy: a systematic literature review. Radiother Oncol. 2003 Mar;66(3):253-62. doi: 10.1016/s0167-8140(02)00404-8 . PMID: 12742264.

⁷ Jensen SB, Peterson DE. Oral mucosal injury caused by cancer therapies: current management and new frontiers in research. J Oral Pathol Med. 2014;43(2):81-90.

⁸ Nonzee NJ, et al. A Review of Clinical Radioprotection and Chemoprotection for Oral Mucositis. Transl Oncol. 2018 Jun; 11(3): 771-778.

⁹ Nonzee NJ, et al. Evaluating the supportive care costs of severe radiochemotherapy-induced mucositis and pharyngitis: results from a Northwestern University Costs of Cancer Program pilot study with head and neck and nonsmall cell lung cancer patients who received care at a county hospital, a Veterans Administration hospital, or a comprehensive cancer care center. Cancer. 2008;113:1146-1152.

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SOURCE: Jaguar Health, Inc.

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