



Napo Pharmaceuticals, a Jaguar Health Family Company, Exhibiting at the Oncology Nursing Society (ONS) Congress for the FDA-Approved Gelclair Oral Mucositis Prescription Product

April 8, 2025

[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

Napo's core target patient audiences for Gelclair are head and neck cancer patients and bone marrow transplant patients

SAN FRANCISCO, CA / [ACCESS Newswire](#) / April 8, 2025 / [Jaguar Health, Inc. \(NASDAQ:JAGX\)](#) ("Jaguar") today announced that Jaguar family company [Napo Pharmaceuticals](#) ("Napo") is exhibiting at the 50th anniversary [Oncology Nursing Society \(ONS\) Congress](#) taking place April 9-13, 2025 in Denver, Colorado as part of ongoing commercial activities for Gelclair.

"We have expanded our footprint beyond HIV-related supportive care to include cancer-related supportive care, and our recent in-licensing of the FDA-approved oral mucositis product Gelclair is a first building block," said Lisa Conte, Jaguar's president and CEO.

"Cancer is chaotic, because patients feel a loss of control - over their life, their treatment, and their supportive care needs," said Conte. "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 look forward to driving awareness among the oncology nursing community at ONS about Gelclair. Oral mucositis, also called "chemo mouth," is among the most common, painful, and debilitating cancer treatment-related side effects, and it 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."

"If it weren't for Gelclair, I don't know if I would have continued with chemo. It was that painful. Gelclair gave me relief when nothing else did - it allowed me to keep going," said Megan-Claire, a Gelclair patient brand ambassador for Napo.

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.



"Nurses play a vital role in providing integrated supportive care to cancer survivors to meet various physical, psychological, and social support needs," added Conte. "Jaguar and Napo acknowledge the rigors of both short-term and chronic treatment and do not believe any cancer therapy-related side effect, whether it is extreme fatigue, debilitating diarrhea, oral mucositis, hair loss, chronic pain, or others, should ever be viewed as 'acceptable' or 'tolerable.' We live in the age of 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."

Napo's core target audiences for Gelclair are head and neck cancer patients and bone marrow transplant patients, and oncology-focused health care professionals. 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 were diagnosed in the U.S. in 2024.² Approximately another 23,000 patients each year undergo bone marrow transplant procedures.

Oral mucositis 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," Conte 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 may require hospitalization and may require parenteral nutrition and IV hydration, and the morbidity and expense associated with those interventions."

Jaguar also remains focused on development of crofelemer for cancer therapy-related diarrhea (CTD). As announced, the analysis of the prespecified subgroup of adult patients with breast cancer from Napo's recently conducted Phase 3 prophylactic [OnTarget](#) clinical trial for diarrhea in adult patients with solid tumors receiving targeted therapy with or without standard chemotherapy indicates that crofelemer achieved statistically significant results in this subgroup. These results were the subject of a December 11, 2024 poster presentation at the [San Antonio Breast Cancer Symposium](#) and the late-breaker abstract recently submitted to the Multinational Association of Supportive Care in Cancer (MASCC) for consideration for presentation at the June 2025 [MASCC Annual Meeting](#). As also announced, the U.S. Food and Drug Administration (FDA) has granted Napo a Type C Meeting in the second quarter of 2025 to discuss the responder analysis in the prespecified subgroup of patients with breast cancer for crofelemer in OnTarget. The company's goal is to discuss the most efficient pathways to make crofelemer available to this patient population for CTD.

The annual ONS Congress is a prominent event for professionals and organizations who are committed to the promotion of excellence in oncology nursing and the transformation of cancer care. ONS is a professional association that represents 100,000 nurses and is the professional home to more than 35,000 members. Since 1975, ONS has provided a professional community for oncology nurses, developed evidence-based education programs and treatment information, and advocated for patient care, all in an effort to improve the quality of life and outcomes for patients with cancer and their families. Learn more at www.ons.org.

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.

Please see full Prescribing Information at:

<https://www.gelclairhcp.com/pdf/prescribing-information-instructions-for-use.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 (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 on [Bluesky](#), [X](#), [Facebook](#) & [Instagram](#)

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 April 2025 ONS Congress, and the expectation that Napo will meet with the FDA in the second quarter of 2025 regarding the statistically significant results of the OnTarget trial in the prespecified subgroup of patients with breast cancer. 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.

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.

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