Vyome Therapeutics Presents Positive Data from Early Analysis of a Phase 2 Study of VT-1953 in Malignant Fungating Wound

VT-1953 significantly improves primary end point and quality of life of patients

CAMBRIDGE, MA, UNITED STATES, January 22, 2025 /EINPresswire.com/ -- • VT-1953 treatment reduces malignant fungating wound-associated malodor over a 14 day period as measured using the TELER scale (primary endpoint) (P=0.0012). Patients reported a 75% reduction in malodor on Day 14 from baseline using a VAS scale and a 50% reduction in lesion pain; VT-1953 was well-tolerated by patients.

- Patients reported improvements in social, functional and emotional states.

- Based on positive results from this study, pivotal studies will start in 2025

Vyome Therapeutics Inc announced the presentation of interim results from its investigator-initiated Phase 2 proof of concept study of VT-1953 topical gel in people with malignant fungating wounds ("MFW")(1). VT-1953, which exerts an immuno-anti-inflammatory effect by targeting TLR-MD2 and DNA gyrase, met its primary endpoint in this interim analysis, with patients exhibiting a significant change from baseline in malodor symptoms associated with MFW. These results were recently presented at the 2024 International Conference of Pharmacology and the 54th Annual Conference of the Indian Pharmacological Society. Full data will be presented later this year.

MFW is a debilitating condition that occurs in 5-14% of advanced cancer patients (2). It is estimated that there are over 693,000 patients with advanced cancer in the US alone and approximately 10M patients globally. Cancer cells break through the skin and cause a chronic wound (MFW), which is extremely distressing to patients given the high burden of symptoms, including extreme malodor, severe pain, a feeling of shame, low self-esteem, and social isolation (2). "Despite the number of patients, there are no FDA-approved options to help treat patients with malignant fungating wounds" said Dr. Shiladitya Sengupta, co-founder of Vyome and Associate Professor of Medicine at Harvard Medical School, "This study shows us those who received VT-1953 had improvement in symptoms, quality of life, and physical function. These findings offer hope that a breakthrough treatment is potentially on the horizon for our patients."

The investigator-initiated Phase 2 study included cancer patients with moderate to severe malodorous MFW. VT-1953 demonstrated a significant reduction in malodor after 14 days, the primary endpoint, scored by clinical investigators using a TELER Odor scale. Before treatment, the baseline median malodor score was 0, i.e. severe malodor detected 10 ft away with dressings on. Post-treatment with VT-1953, 100% of the patients had a score of 4, i.e. mild odor detected less than 3 ft away only after removing the dressing, a robust reduction from the baseline score (P=0.0012). Improvements across multiple domains of the MFW phenotype were reported by patients, including a reduction in malodor (75%, P=0.0003), and lesion pain (50%, P=0.05) scored on a visual analog scale, and in social interactions, function, and emotional state over the 14 days on a Quality of Life analysis, which served as secondary and exploratory endpoints. No clinically significant adverse trends were noted with VT-1953 administration (1).

“I regularly see cancer patients who are struggling with the symptoms of MFW, especially in soft tissue sarcomas. Although these are early signals from the VT-1953 trial, this kind of efficacy could be transformative for these patients. This is a huge unmet need”, said Dr. Sant Chawla MD, a leading oncologist and director of the Sarcoma Oncology Center in Santa Monica, CA, who was not involved with the trial.

Venkat Nelabhotla, CEO of Vyome, stated that “Based on these positive results, Vyome Therapeutics is aiming to design pivotal studies and will interact with regulators in 2025 after the completion of a potential merger with Reshape Lifesciences (“RSLS”) to be listed as Vyome Holdings, Inc. (“HIND”). Vyome looks forward to advancing this program as part of its broader chronic immune-inflammation portfolio.

About Malignant Fungating Wounds
Malignant Fungating Wound (MFW) is a complex, debilitating, and distressing condition that is estimated to affect about 5-14% of advanced cancer patients (2). Cancer breaks through the skin forming a chronic wound that smells so offensive that it can often be detected over 10 ft away, and is distressing for the patient and the caregivers (3). Patients also suffer from pain in the lesion area. These symptoms reduce patients’ ability for daily functions, leading to social withdrawal, depression, and impaired quality of life. Addressing these symptoms can significantly improve the quality of life of patients. Despite its severity, there are no FDA-approved treatments for the symptoms of MFW. Vyome Therapeutics aims to develop VT-1953 with the goal of addressing this unmet medical need and impacting the lives of these patients.

(1) Lad PP, Sengupta S. Early clinical results testing efficacy and safety of VT-1953 topical gel in treating symptoms of malodorous malignant fungating wound. (IPSCON24 Abstract#D7838).
(2) Vardhan M, et al. The Microbiome, Malignant Fungating Wounds, and Palliative Care. Front Cell Infect Microbiol. 2019;9:373. doi: 10.3389/fcimb.2019.00373
(3)Alexander, S.J. An intense and unforgettable experience: the lived experience of malignant wounds from the perspectives of patients, caregivers and nurses. International Journal of Woundcare. 2010, 7:456-465

About VT-1953
VT-1953 topical gel is designed to treat the symptoms of MFW by targeting the cause of malodor and inhibiting the drivers of inflammation. In prior clinical studies, VT-1953 topical gel has been well tolerated in over 400 patients. The current results showed encouraging signals of efficacy against symptoms of MFW in both investigator- and patient-reported outcomes.

About Vyome Therapeutics:
Vyome Therapeutics is building a healthcare platform spanning the US-India innovation corridor. Vyome's immediate focus is leveraging its clinical-stage assets to transform the lives of patients with immune-inflammatory conditions. By applying groundbreaking science and its unique positioning across the US-India innovation corridor, Vyome seeks to deliver lasting value to shareholders in a hyper cost-efficient manner while upholding global standards of quality and safety. Based in Cambridge, MA, the company has announced its intent to be listed on the Nasdaq exchange under the ticker 'HIND' pursuant to a reverse merger with ReShape Lifesciences Inc. (Nasdaq: RSLS) in early 2025. To learn more, please visit www.vyometx.com

Forward-Looking Statements
Certain statements made in this press release are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words such as "target," "believe," "expect," "will," "shall," "may," "anticipate," "estimate," "would," "positioned," "future," "forecast," "intend," "plan," "project," "outlook", and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Examples of forward-looking statements include, among others, statements made in this report regarding the merger, including the benefits of the merger, revenue opportunities, anticipated future financial and operating performance, and results, including estimates for growth, and the expected timing of the merger. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on management's current beliefs, expectations, and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of Vyome's control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, the following: (a) the occurrence of any event, change, or other circumstances that could give rise to the termination of the merger; (b) failure to obtain the necessary consents and approvals, including the approval of ReShape's stockholders; (c) the inability to complete the Merger or satisfy other closing conditions; (d) the risk that the merger disrupts current plans and operations as a result of the announcement and consummation of the merger; (e) the approval of the continued listing application of ReShape to have the common stock of the combined company continue to be traded on Nasdaq; (f) costs related to the merger; and (g) changes in applicable laws or regulations. Vyome cautions that the foregoing list of factors is not exhaustive. Vyome cautions readers not to place undue reliance upon any forward-looking statements,

which speak only as of the date made. Vyome does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based, whether as a result of new information, future events, or otherwise, except as may be required by applicable law.

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