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Vyome inches towards US FDA approval to enter $1B worth malignant fungating wound market

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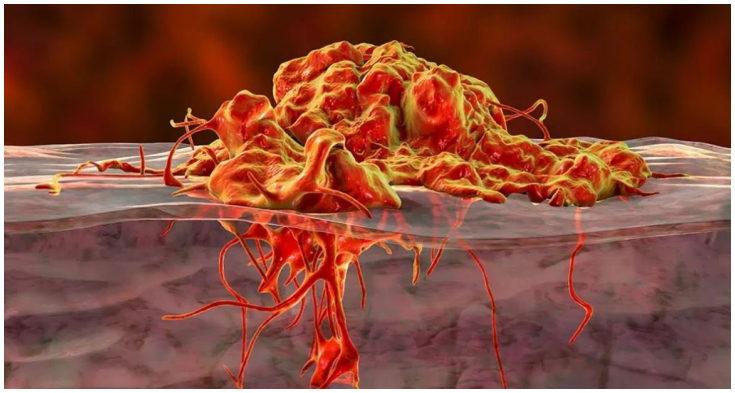
Vyome reports positive final Phase 2 results for VT-1953



Vyome Holdings, Inc., based both in US and India, has announced the final results from an investigator-initiated Phase 2 proof of concept study of VT-1953 topical gel in people with malignant fungating wounds (MFW).

VT-1953, a first-in-class immunomodulator for this indication, achieved both its primary and secondary endpoints. With this result, Vyome plans to advance to Phase III pivotal trial, seek US FDA approval, and enter the $1 billion potential addressable market as the only anticipated approved solution for malignant fungating wounds.

MFW is a debilitating condition that occurs in 5-14% of advanced cancer patients. It is estimated that there are over 693,000 patients with advanced cancer in the US alone and approximately 10 million globally.

Venkat Nelabhotla, CEO of Vyome, stated that “these positive results reinforce the potential of VT1953, and we are now preparing to engage with the FDA to design and initiate a pivotal Phase III clinical study in 2026. Over the past several months, we have strengthened our team with top-tier clinical, regulatory, and scientific leaders who bring deep experience in advancing differentiated therapies. This positions us well for disciplined execution as we move into the next phase of development. Vyome remains well capitalized through 2026, allowing us to advance VT1953, a potentially orphan designation program, as a part of our broader chronic immune-inflammation portfolio. We look forward to progressing this program thoughtfully and responsibly toward its next key milestones.”