

Press Release

For Immediate Release

Glenmark Pharmaceuticals and SaNOtize Announce Peer Reviewed Publication of Its Phase 3 Clinical Trials on SaNOtize's Novel Nitric Oxide Nasal Spray for COVID-19 in Lancet Journal

- *The Lancet Regional Health Southeast Asia* publishes the successful phase 3 clinical trial results of Nitric Oxide Nasal Spray.
- *Phase 3 trial of Nitric Oxide Nasal Spray administered to adult COVID-19 patients in India met the key endpoints and demonstrated reductions of viral load of 94% in 24 hours and 99% in 48 hours.*
- *Nitric Oxide Nasal Spray was safe and well tolerated in COVID-19 patients.*
- *Following positive results and regional approvals, Glenmark launched this nasal spray in India under the brand name FabiSpray® and in Singapore and Hong Kong under the brand name VirX™.*

Mumbai, India, & Vancouver, British Columbia, July 13, 2022: Glenmark Pharmaceuticals Limited (Glenmark), an innovation-driven, global pharmaceutical company, and SaNOtize Research and Development Corp, today announced that *The Lancet Regional Health Southeast Asia (TLRHSEA)* – peer reviewed, high impact journal published the successful phase 3 clinical trial results of SaNOtize's Nitric Oxide Nasal Spray (NONS) study titled: "SARS-CoV-2 accelerated clearance using a novel nitric oxide nasal spray (NONS) treatment: A randomized trial.

[https://www.thelancet.com/journals/lansea/article/PIIS2772-3682\(22\)00046-4/fulltext](https://www.thelancet.com/journals/lansea/article/PIIS2772-3682(22)00046-4/fulltext)

"We are excited to publish the study of the novel Nitric Oxide Nasal Spray, which positively impacts the lives of people, in The Lancet group of journals. The robust double-blind trial demonstrated significant efficacy and remarkable safety of NONS. This therapy has the potential to make a crucial contribution to COVID-19 management, with its ease of use in the current highly transmissible phase of pandemic", said Dr. Monika Tandon, Senior VP & Head - Clinical Development, Glenmark Pharmaceuticals Ltd.

The study demonstrated that patients who received NONS had significant reduction in viral load within 24 hours, which was sustained over seven days of treatment. Viral load was reduced by 93.7% within 24 hours and by 99% within 48 hours of treatment with NONS. The average change from baseline in log viral RNA load through the entire treatment duration was statistically superior with NONS compared to placebo. Similar results were observed in vaccinated and unvaccinated populations. The study was conducted during the delta and omicron surges. Key secondary endpoints including clinical improvement assessed by WHO Clinical Progression Scale Score and extent/rapidity of virologic recovery was demonstrated in patients using NONS. The median time to virological cure was three days in the NONS group and seven days in the placebo group after start of treatment (four days sooner). The exploratory evaluation of the proportion of immediate contacts having a positive COVID-19 test or becoming symptomatic, remained nearly the same in the NONS group while it numerically increased in the placebo group over the treatment.

"The Phase 3 study results strongly support the safety and efficacy of NONS in the treatment of COVID-19 and its known variants," said Gilly Regev, PhD, SaNOtize Co-Founder and CEO. "Nitric oxide blocks entry into the nasal passage, kills the virus, and stops its replication, which is why viral load is reduced so rapidly with NONS. Viral load has been linked to infectivity, poorer health outcomes, and complications from long COVID. The evidence is mounting that NONS represents an effective, well tolerated antiviral treatment that significantly shortens the course of COVID-19."

Study Design

The study was conducted by Glenmark in 306 vaccinated and non-vaccinated adults of symptomatic mild COVID -19 across 20 clinical sites in India. This randomized, double-blind phase 3 clinical trial evaluated a seven-day treatment of NONS plus standard of care versus placebo nasal spray plus standard care in patients with symptomatic COVID-19. The primary outcome measure of nasal SARS-CoV-2 RNA accelerated clearance was used to assess the efficacy of this transformational NONS in high-risk patients (unvaccinated, or 45 years of age, or had one or more comorbidities) after seven days of treatment. Exploratory evaluation of NONS in prevention of infection in immediate contacts of these COVID-19 patients was also evaluated.

NONS treatment was found to be well tolerated, establishing an advantage of locally acting nasal therapy. None of the patients reported any moderate or severe adverse events. There were no clinically significant changes from baseline observed in methemoglobin suggesting lack of systemic availability of nitric oxide from nasal spray. Additionally, neither nasal vasodilation symptoms nor systemic vasodilation signs were observed in either treatment.

Strategic Partnership with SaNOtize

In July 2021, Glenmark entered into an exclusive long term strategic partnership with Canadian biotech firm SaNOtize, to manufacture, market and distribute its breakthrough Nitric Oxide Nasal Spray for COVID-19 treatment in India and other Asian markets including Singapore, Malaysia, Hong Kong, Taiwan, Nepal, Brunei, Cambodia, Laos, Myanmar, Sri Lanka, Timor-Leste and Vietnam.

Global Approvals for NONS

Glenmark launched NONS under the brand name FabiSpray® in February 2022, after receiving manufacturing and marketing approval from the Drugs Controller General of India (DCGI) as part of the accelerated approval process. NONS has already received a CE mark in Europe, which is an equivalent of marketing authorization in case of a Medical Device. By virtue of the CE mark, SaNOtize has permission to launch NONS in the EU. NONS is also approved and being sold in Singapore, Hong Kong, Israel, Thailand, Indonesia and Bahrain, under the name enovid™ or VirX™. Outside of India, NONS has also been approved globally for protection against viruses, including SARS COV-2.

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About Glenmark Pharmaceuticals Ltd

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is an innovation-driven global pharmaceutical company with a presence across Specialty, Generics and OTC businesses. It focuses on the key therapeutic areas of respiratory, dermatology and oncology. The company has 10 world-class manufacturing facilities spread across 4 continents and operations in over 80 countries. Glenmark is ranked among the world's top 100 biopharmaceutical companies (Top 100 Companies Ranked by Pharmaceutical Sales, 2020, by In Vivo/Scrip 100) and among the world's top 50 companies in the off-patent sector (Top 50 Generics and Biosimilars Companies ranked by Sales, 2020, by Generics Bulletin/In Vivo). The company was listed on the Dow Jones Sustainability Index (DJSI), one of the world's most respected and widely accepted sustainability benchmarks, under the category of emerging markets (2021) for the fourth consecutive year. For more information, visit www.glenmarkpharma.com.

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About SaNOtize

SaNOtize Research & Development Corp. is a pharmaceutical company based in Vancouver, BC, commercializing the multi-faceted antimicrobial properties of a liquid producing nitric oxide. The company has developed and patented a Nitric Oxide Releasing Solution platform technology (NORS™) to treat and prevent upper respiratory and topical infections. For more information, visit www.SaNOtize.com. Follow us on social: [LinkedIn](#), [Twitter](#).

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