February 9, 2022

**To,**
**Dy. General Manager**
**Department of Corporate Services,**
**BSE Ltd.,**
**P. J. Towers, Dalal Street,**
**Fort, Mumbai – 400 001.**

**Ref: Scrip Code: 532296**

**To,**
**The Manager – Listing,**
**The National Stock Exchange of India Ltd.,**
**Plot No. C/1, G Block,**
**Bandra Kurla Complex,**
**Bandra (E), Mumbai – 400 051.**

**Ref: Scrip Name: GLENMARK**

Dear Sir,

**Sub: Glenmark launches Nitric Oxide Nasal Spray (FabiSpray®) in India for the Treatment of Adult Patients with COVID-19 in partnership with SaNOtize**

With reference to the subject mentioned above, kindly find attached media release which is self-explanatory.

Request you to kindly take the same on record.

Thanking you,

Yours faithfully,
**For Glenmark Pharmaceuticals Limited**

HARISH VINAYAK KUBER
Digitally signed by HARISH VINAYAK KUBER
Date: 2022.02.09 08:27:47 +05'30'

**Harish Kuber**
**Company Secretary & Compliance Officer**

**Encl:** as above

**Press release** **For immediate distribution**

# Glenmark launches Nitric Oxide Nasal Spray (FabiSpray®) in India for the Treatment of Adult Patients with COVID-19 in partnership with SaNOtize

- *Glenmark received manufacturing and marketing approval from India's drug regulator for Nitric Oxide Nasal Spray (NONS) as part of accelerated approval process.*
- *Phase 3 trial in India met the key endpoints and demonstrated reduction of viral load of 94% in 24 hours and 99% in 48 hours.*
- *NONS was safe and well tolerated in COVID-19 patients.*
- *Glenmark to market NONS under the brand name FabiSpray®.*

**Mumbai, India; February 09, 2022:** Glenmark Pharmaceuticals Limited (Glenmark) – a global, innovation-driven pharmaceutical company and Canadian pharmaceutical company SaNOtize Research & Development Corp. today announced launch of its Nitric Oxide Nasal Spray under the brand name FabiSpray® in India; for the treatment of adult patients with COVID-19 who have high risk of progression of the disease. Glenmark earlier received manufacturing and marketing approval from the Drugs Controller General of India (DCGI) for NONS as part of the accelerated approval process.

**FabiSpray®**

FabiSpray®, Nitric Oxide Nasal Spray, is designed to kill the COVID-19 virus in the upper airways. It has proven anti-microbial properties with a direct virucidal effect on SARS-CoV-2. NONS when sprayed over nasal mucosa acts as a physical and chemical barrier against the virus, preventing it from incubating and spreading to the lungs.

***Commenting on the significance of this development, Robert Crockart, Chief Commercial Officer, Glenmark Pharmaceuticals Ltd. said, "As a leading pharmaceutical player, it is important that we are an integral part of India's fight against the COVID-19 pandemic. We are happy to receive regulatory approval for Nitric Oxide Nasal Spray (FabiSpray®) and launch it in partnership with SaNOtize. This reaffirms our commitment of providing yet another safe and effective antiviral treatment for COVID-19, and we are confident it will offer patients a much needed and timely therapy option."***

**Indian Phase 3 Clinical Trial Outcomes**

- A Phase 3 clinical trial was conducted in adult COVID-19 patients across 20 clinical sites in India. The double-blind, parallel arm, multicenter study, conducted in 306 patients evaluated the efficacy and safety of Nitric Oxide Nasal Spray versus normal saline nasal spray in non-hospitalized adult patients. All patients received standard supportive care in the study.
- The trial analyzed patients with risk of progression of disease - non-vaccinated patients, patients in the middle and older age group and patients with co-morbidities.
- Primary endpoint was met: Reduction in log viral load in the NONS group was statistically significant and superior to the control (placebo) group ($p < 0.05$).
- The median time to virological cure was 4 days in the NONS group and 8 days in the placebo group ($p < 0.05$).
- A significantly higher proportion of patients demonstrated a 2-point improvement on the WHO Progression Scale (a validated clinical endpoint) in the NONS group as compared to the placebo group ($p < 0.05$).

- NONS was safe and well tolerated by patients. No patients experienced moderate, severe, serious Adverse Events (AE) or death in the study.

***Dr. Monika Tandon, Senior VP & Head - Clinical Development, Glenmark Pharmaceuticals Ltd., commented: "The results from this Phase 3, double blind, placebo controlled trial are encouraging. Demonstration of reduction in the viral load has significant positive impact from a patient and community perspective. In the current scenario, with new emerging variants exhibiting high transmissibility, NONS provides a useful option in India's fight against COVID-19."***

In March 2021, clinical trials from its innovator, SaNOtize showed NONS was a safe and effective antiviral treatment of SARS CoV-2. In the first 24 hours, NONS reduced the average viral load by around 95%, and then by more than 99% within 72 hours. (In the India Phase 3 trial, a reduction of viral load of 94% in 24 hours and 99% in 48 hours was similar to reduction seen in the UK NHS trial conducted by SaNOtize). NONS has been tested in healthy volunteers and patients as part of Canada and UK clinical trials. SaNOtize has an ongoing global Phase 3 prevention trial, which will further add to its efficacy. As per studies conducted in the Utah State University USA, NONS is proven to kill 99.9% of SARS-Cov-2 virus including Alpha, Beta, Gamma, Delta, and Epsilon variant within 2 minutes.

***Dr. Srikanth Krishnamurthy one of the Principal Investigators of the study commented, "I have had a chance to view the results of the study. Nitric Oxide Nasal Spray lowers the viral load and hastens RT-PCR negativity when used early in COVID 19 infection leading to recovery. Most importantly, viral load reduction with NONS has the potential to reduce the chain of transmission. Last but not the least, NONS being topical, is safe, and makes this therapeutic option very attractive".***

**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**

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 Israel, Thailand, Indonesia and Bahrain, under the name enovid™ or VirX™. NONS is approved in many counties for protection against viruses including SARS COV-2.

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**About Glenmark Pharmaceuticals Ltd**

Glenmark Pharmaceuticals Ltd. (GPL) is a global innovation-driven pharmaceutical company with presence across Specialty, Generics and OTC businesses. Globally, Glenmark focuses on the following key therapy areas: respiratory, dermatology and oncology. The company has 10 world class manufacturing facilities spread across 4 continents and operations in over 80 countries. It was ranked among the world's top 50 Generics and Biosimilars companies (Top 50 Company Rankings, 2020, from Informa's Generics Bulletin). The company has been listed on the Dow Jones Sustainability Index (DJSI), under the category of emerging markets for the fourth consecutive year in a row, most recently in 2021. DJSI is one of the world's most respected and widely accepted sustainability benchmarks globally with only the top ranked companies in terms of Corporate Sustainability within each industry are featured in the index. For more information, visit www.glenmarkpharma.com

**For more information, please contact**

Udaykumar Murthy
Deputy General Manager, Corporate Communications
+91 9960377617 | corpcomm@glenmarkpharma.com