SaNOtize Obtains Health Canada Approval to Commence Phase II Trial for Potential COVID-19 Therapy

New Laboratory Tests Conducted by Utah-Based Institute for Antiviral Research Confirm SaNOtize’s Nitric Oxide Releasing Solution (NORS™) is Over 99.9% Effective Against SARS-CoV-2, the Virus that Causes COVID-19

VANCOUVER, BC, April 22, 2020 — SaNOtize Research and Development Corporation ("SaNOtize" or "the company") today announced that it has been granted approval by Health Canada to conduct a multi-Centre Phase II prevention and efficacy trial for a front-line antiviral prevention and early treatment for use against COVID-19.

SaNOtize also announced that new tests conducted by the Institute for Antiviral Research at Utah State University confirm SaNOtize’s Nitric Oxide Releasing Solution (NORS™) inactivated more than 99.9% of SARs-CoV-2, the virus that causes COVID-19, within two minutes, in laboratory tests.

SaNOtize has been evaluating nitric oxide (NO), a naturally occurring nanomolecule, as a first-in-class drug with the potential to be used as a topical antimicrobial agent to treat a wide variety of bacterial, viral and fungal diseases, including COVID-19. The company has been granted US and EU patents on a Nitric Oxide Releasing Solution (NORS™), and is testing ready-to-use, inexpensive and rapidly-scalable applications delivered through gargle solutions, nasal spray and nasal lavage.

“We are grateful for Health Canada’s rapid response and are moving as quickly as possible to conduct Phase II trials here in Canada, with a focus on frontline healthcare workers and other individuals at greatest risk of infection,” said Chief Science Officer and co-founder, Dr. Chris Miller. “If our Phase II results confirm our earlier work, including the very encouraging results just received from the Antiviral Research Institute, we will be seeking emergency approval in Canada to proceed directly to Phase IV introduction of our product to the market as part of the global fight against this deadly pandemic. At the same time, we are seeking Emergency Use Authorization from the FDA so that we can make NORS™ available to healthcare workers and other high-risk individuals in the US on an expedited basis.”

Repeated application of NORS™ has been demonstrated to be safe and potentially effective in patients with chronic sinusitis. Further trials have demonstrated its effectiveness in-vitro against viruses, including influenza A, hCoV-OC43 and H1N1. The company has robust data demonstrating NORS has a rapid and significant virucidal effect against Influenza A virus (6 log reduction within 30 seconds). Data from these trials has provided a strong foundation to suggest that application of NORS™ may have considerable impact in addressing the COVID-19 pandemic. Specifically, SaNOtize believes that by reducing the risk of infection, daily use of NORS can help facilitate the gradual resumption of social and economic activity while we wait for a vaccine to be developed.

Dr. Ferid Murad, a recipient of the 1998 Nobel Prize in Physiology or Medicine for the discovery that nitric oxide acts as a signalling molecule in the cardiovascular system, and a member of the SaNOtize Board of Directors, said, "Nitric oxide is an incredibly versatile molecule that regulates almost everything in our body. When used therapeutically, it has a well-documented safety profile and is demonstrated to be effective against a wide variety of viruses, bacteria and fungi. I’m excited to be working with the SaNOtize team and believe that they have a safe technology that could be effective in treating infections, including COVID-19."
“Our goal has long been to find a way to use Nitric Oxide’s antimicrobial properties to improve human health,” said Dr. Gilly Regev, SaNOtize CEO and co-founder. “We are working around the clock to achieve that goal in time to help with the fight against COVID-19.”

The pharmacology, toxicity, and safety data for NO in humans is well-established. The NO produced from NORS™ is an identical molecule to nitric oxide naturally produced by the human body, and to the nitric oxide that has a drug approval by the FDA for the treatment of premature infants with acute pulmonary hypertension. There is no biochemical, pharmacokinetic or physical difference between them.

SaNOtize is currently in discussions with suppliers and potential partners to rapidly scale up production of NORS in North America upon receipt of regulatory approval. NORS™ is formulated from readily available USP grade ingredients from multiple sources. High volume scale-up could be done rapidly in an extremely cost-effective manner. Shelf-life and stability have been determined to be one year in the appropriate container.

For more information about SaNOtize, NORS™, and our efforts to bring to market antiviral nasal spray, gargle treatment and deep sinus wash products for use in the fight against COVID-19, please visit our website or download our discussion paper.

About SaNOtize
SaNOtize Research & Development Corp. is a biotech company based in Vancouver, BC working to commercialize 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 microbial infections.

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