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Clinical Trial Confirms Breakthrough Treatment for COVID-19

Randomized, double-blind, placebo-controlled trial evaluated 79 confirmed cases of COVID-19, the majority heavily-infected with the UK variant.

By Business Wire
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Patients with a self-administered nasal spray application found to have reduced SARS-CoV-2 log viral load by more than 95% in infected participants within 24 hours of treatment, and by more than 99% in 72 hours

Trial concluded that treatment accelerated clearance of SARS-CoV-2 by a factor of 16-fold versus a placebo

Randomized, double-blind, placebo-controlled trial evaluated 79 confirmed cases of COVID-19, the majority heavily-infected with the UK variant

No adverse events were recorded in the group

Submission for Emergency Use in the UK and Canada for the treatment and prevention of COVID-19 is planned immediately

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Biotech company SaNOtize Research & Development Corp., (SaNOtize), Ashford and St Peter's Hospitals NHS Foundation Trust in Surrey, UK, and Berkshire and Surrey Pathology Services, UK, on Thursday announced results of clinical trials indicating that SaNOtize's Nitric Oxide Nasal Spray (NONS) represents a safe and effective antiviral treatment that could prevent the transmission of COVID-19, shorten its course, and reduce the severity of symptoms and damage in those already infected.

In a randomized, double-blind, placebo-controlled Phase 2 trial that evaluated 79 confirmed cases of COVID-19, SaNOtize's early treatment for COVID-19 significantly reduced the level of SARS-CoV-2, including in patients with high viral loads. The average viral log reduction in the first 24 hours was 1.362, which corresponds to a decline of about 95%. Within 72 hours, the viral load dropped by more than 99%. The majority of these patients had been infected with the UK variant, which is considered a variant of concern. There were no adverse health events recorded in the UK trial, or in over 7,000 self-administered treatments given in earlier Canadian clinical trials.

NONS is the only novel therapeutic treatment so far proven to reduce viral load in humans that is not a monoclonal antibody treatment. Monoclonal antibodies are highly specific, expensive and must be administered intravenously in a clinical setting.

> "I expect this to be a major advance in the global battle against the devastating human impacts of the COVID-19 pandemic," said **Dr. Stephen Winchester**, Consultant Medical Virologist and Chief Investigator of this NHS Clinical Trial. "This simple portable nasal spray could be highly effective in the treatment of COVID-19 and reducing onward transmission. Our trial included patients with a variant of concern and high viral loads yet still demonstrated significant reductions in the levels of SARS-CoV-2, which could be critical in supporting vaccines, preventing future outbreaks and safely reopening economies. Simply stated, I think this could be revolutionary."

The SaNOtize treatment is designed to kill the virus in the upper airways, preventing it from incubating and spreading to the lungs. It is based on nitric oxide (NO), a natural nanomolecule produced by the human body with proven anti-microbial properties shown to have a direct effect on SARS-CoV-2, the virus that causes COVID-19. The pharmacology, toxicity, and safety data for NO use in humans has been well-established for decades. The NO molecule released from NONS is identical to the one delivered in its gaseous form to treat persistent pulmonary hypertension, or Blue Baby Syndrome, in newborn babies.

SaNOtize Seeking Emergency Use Authorization in UK and Canada

SaNOtize is applying to regulatory authorities in the UK and Canada for Emergency Use authorization. Swift approval and ramp-up of manufacturing could facilitate an almost immediate safe return to work, school and society, and spur an economic recovery that is months – if not years – ahead of full global vaccination.

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