



NRx Pharmaceuticals Announces Emergency Use Authorization of ZYESAMI™ (aviptadil) in Nation of Georgia

-- More than One Thousand New Cases of COVID-19 Diagnosed Every Day in Georgia, With Increasing Detection of the Delta Variant

-- Association of Georgian Physicians Unanimously Supports Regulatory Decision

-- Training of Georgian Doctors in use of ZYESAMI™ (aviptadil) to Begin Within 24 Hours

RADNOR, Pa., July 27, 2021 /[PRNewswire](#)/ -- NRx Pharmaceuticals (Nasdaq: NRXP) (NRx), a clinical stage, global biopharmaceutical company, today announced that the Nation of Georgia's Prime Minister and Minister of Health have issued an Emergency Use Authorization for intravenous ZYESAMI™ (aviptadil) for the treatment of Critical COVID-19.

<div style="border-bottom: 1px solid black; padding-bottom: 5px;">NRx Pharmaceuticals Announces Emergency Use Authorization of ZYESAMI™ (aviptadil) in Nation of Georgia</div>	"Lead investigators from our ZYESAMI™ clinical trials are on their way to the Nation of Georgia and will be on the ground there within 24 hours to start teaching physicians how to administer ZYESAMI™ to some of the sickest of COVID patients," said Prof. Jonathan Javitt, MD, MPH, Chief Executive Officer and Chairman of the Board of NRx. "The repeating ferociousness of this pandemic is of great concern, and we hope ZYESAMI™ can have a real-world impact, comparable to what we saw in our clinical trials."
--	--

The regulatory approval comes as Georgian doctors are seeing significant, daily increases in COVID-19 cases, hospitalized patients, and specifically, patients in hospital intensive care units.

"This latest wave of COVID-19, brought on by the delta variant has medical professionals in Georgia working throughout each day and night trying to keep people breathing," said Dr. Ivane Chkhaidze, a leading pulmonary physician in Georgia and a member the Association of Georgia Physicians Leadership Team. "We appreciate the Prime Minister and Minister of Health authorizing the use of ZYESAMI™ and offering Georgian physicians a new treatment to help people recover from this devastating virus."

Dr. Javier Perez-Fernandez, a lead investigator in the Phase 2b/3 clinical trial of intravenous ZYESAMI™ (aviptadil), and critical care pulmonologist in Miami, Florida, is leading the team of physicians traveling to Georgia to train fellow doctors there about administering ZYESAMI™ and the effects of the medicine. The first Georgian physicians trained in administering ZYESAMI™ comprise twenty of the leading critical care physicians in the country.

The first doses of ZYESAMI™ will arrive in the Nation of Georgia within 24 hours, and discussions are underway with the Ministry of Health to provide access to ZYESAMI™ to Georgians suffering with Critical COVID-19.

About ZYESAMI™/VIP in COVID-19

ZYESAMI™ (aviptadil) is a synthetic form of Vasoactive Intestinal Polypeptide (VIP) first discovered by the late Prof. Sami Said in 1970, and ZYESAMI™ is named in his honor. Although primarily concentrated in the lung, it was first purified from the intestinal tract. VIP binds specifically to the alveolar type II cell (ATII) in the air sac

(alveolus) of the lung, where it has been shown have potent anti-inflammatory/anti-cytokine activity in animal models of respiratory distress, acute lung injury, and inflammation. VIP stimulates ATII cells to make the surfactant that must coat the lining of the lungs in order for them to exchange oxygen with the blood. Loss of surfactant causes respiratory failure and alveolar collapse, which are hallmarks of COVID-19.

COVID-19-related respiratory failure is caused by selective infection of the ATII cell by the SARS-CoV-2 virus. The ATII cells are vulnerable because of their (ACE2) surface receptors, which serve as the route of entry for the virus. Coronavirus infection of the ATII cell shuts down surfactant production, triggers the formation of inflammatory cytokines, and causes cell death (cytopathy). VIP is shown to upregulate surfactant production, block Coronavirus replication in the ATII cell, block cytokine synthesis, and prevent viral-induced cell death (cytopathy). Other than ZYESAMI™, no currently proposed treatments for COVID-19 specifically target this mechanism of action.

About NRx Pharmaceuticals

NRx Pharmaceuticals (www.nrxpharma.com) (NRx) draws upon more than 300 years of collective, scientific and drug-development experience to bring improved health to patients. Its investigational product, ZYESAMI™ (aviptadil) for patients with COVID-19, has been granted Fast Track designation by the US Food and Drug Administration (FDA) and is currently undergoing phase 3 trials funded by the US National Institutes of Health, the Biomedical Advanced Research and Development Authority part of the US Department of Health and Human Services, and the Medical Countermeasures program, part of the US Department of Defense. The FDA has additionally granted Breakthrough Therapy Designation, a Special Protocol Agreement, and a Biomarker Letter of Support to NRx for NRX-101, an investigational medicine to treat suicidal bipolar depression. NRX-101 is currently in Phase 3 trials, with readouts expected in 2022.

NRx is led by executives who have held senior roles at Allergan, J&J, Lilly, Novartis, Pfizer, and the US FDA. NRx is chaired by Jonathan Javitt, MD, MPH, who has held leadership roles in six biotechnology startup companies with public exits and been appointed to advisory roles in four US Presidential administrations. The NRx board includes Dr. Sherry Glied, former US Assistant Secretary for Health (ASPE), Daniel E. Troy, JD, former Chief Counsel of the US FDA, Chaim Hurvitz, former director of Teva and President of the Teva International Group, and General H.R. McMaster, Ph.D. (US Army, Ret.) the 26th United States National Security Advisor.

Cautionary Note Regarding Forward-Looking Statements

This announcement of NRx Pharmaceuticals, Inc. includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995, which may include, but are not limited to, statements regarding our financial outlook, product development, business prospects, and market and industry trends and conditions, as well as the company's strategies, plans, objectives, and goals. These forward-looking statements are based on current beliefs, expectations, estimates, forecasts, and projections of, as well as assumptions made by, and information currently available to, the company's management.

The company assumes no obligation to revise any forward-looking statement, whether as a result of new information, future events or otherwise. Accordingly, you should not place reliance on any forward-looking statement, and all forward-looking statements are herein qualified by reference to the cautionary statements set forth above.

CORPORATE CONTACT

Jack Hirschfield
Head of Corporate Communications, NRx
jhirschfield@nrxpharma.com
512-674-5163

INVESTOR RELATIONS

John Mullaly
LifeSci Advisors
jmullaly@lifesciadvisors.com
617-429-3548

View original content to download multimedia:<https://www.prnewswire.com/news-releases/nrx-pharmaceuticals-announces-emergency-use-authorization-of-zyesami-aviptadil-in-nation-of-georgia-301342316.html>

C

SOURCE NRx Pharmaceuticals

Released July 27, 2021

Additional assets available online:  [Photos \(1\)](#)

View original content to download multimedia <https://ir.nrxpharma.com/2021-07-27-NRx-Pharmaceuticals-Announces-Emergency-Use-Authorization-of-ZYESAMI-TM-aviptadil-in-Nation-of-Georgia>