NRx Pharmaceuticals Announces Initiation of Phase 2b Trial of BriLife™ Vaccine for Covid-19 in Nation of Georgia

August 9, 2021
-Dose-Confirmatory Trial Follows Successful Phase 2a Trial
-Preclinical and Early Human Data Indicate BriLife™ May Confer Enhanced Immunity Against Delta variant

RADNOR, Pa., Aug. 9, 2021 /PRNewswire/ -- NRx Pharmaceuticals (NRx) (Nasdaq: NRXP), a clinical stage, global biopharmaceutical company today announced it is initiating a phase 2b dose-confirmatory trial of the BriLife™ vaccine against COVID-19 in the Nation of Georgia. The vaccine is developed by the Israel Institute for Biological Research (IIBR). The trial is being conducted with oversight from the Senator Richard Lugar Center for Public Health Research. The purpose of the study is to confirm the vaccine's ability to generate an immune response against the COVID-19 Delta variant, prior to entering phase 3 trials in multiple nations. The phase 2b program will also incorporate a potential intradermal vaccination option where a small quantity of vaccine is placed into the skin instead of a traditional needle injection into a muscle.

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The vaccine differs from other COVID-19 vaccines by presenting the entire COVID-19 spike protein to the body's immune system. The spike protein complex from variants may be added to the BriLife vaccine as new variants are discovered.

The BriLife™ vaccine also differs from other COVID-19 vaccine approaches in that it is a self-propagating, live-virus vaccine that may be updated to address new variants of COVID-19 more rapidly than some other vaccine platforms. The clinical trials in Georgia will take place at the same time as the completion of the second phase of clinical trials in Israel. NRx is recruiting volunteers, and expanding the second phase of clinical trials abroad, in order to increase the statistical sample and prepare the regulatory file necessary for further trials.

A spokesperson for Israel's Minister of Defense stated today that, "IIBR will accompany the process and will continue to provide scientific knowledge in order to complete the trials."

"We at NRx are honored to have been selected for this project and grateful for the trust placed in us by the Government of Israel, the people of Georgia, and its neighboring countries," said Prof Jonathan Javitt, MD, MPH, CEO and Chairman of NRx. "As the Delta and subsequent variants continue to threaten the immunity generated by first-generation vaccines, we hope that this new vector-based approach may offer enhanced immunity."

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. In July 2021, the Government of Israel awarded NRx the exclusive worldwide right to develop and market the BriLife™ COVID vaccine developed by the Israel Institute for Biological Research.

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 Prof 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 External Affairs, NRx
jhirschfield@nrxpharma.com
512-674-5163

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

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