December 6, 2021

NRx Announces Completion of Data Safety Meeting for Phase 2 Trial of BriLife Vaccine, Phase 2b/3 Registration Trial to Begin in Nation of Georgia, Israel, European Union, and Other Regions

•Independent Data Safety Monitoring Board has completed review of BriLife phase 2 trial at low, medium, and high doses, with a formal report expected imminently
•NRx has obtained advice from European Medicines Authority and World Health Organization on phase 2b/3 registration trial protocol
•More than 10 countries have reached out to express interest in participation

RADNOR, Pa., Dec. 06, 2021 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals (NASDAQ:NRXP), today was advised that the independent Data Safety Monitoring Board overseeing the phase 2 trial of the BriLife™ vaccine has concluded its safety analysis. A formal report is expected in the coming days. Based on the input received, NRx is proceeding with its plans to initiate a phase 2b/3 registration trial of BriLife (see www.clinicaltrials.gov NCT04990466). NRx, working in concert with Cromos, LLC has received guidance in design of the trial from the European Medicines Agency and the World Health Organization.

The BriLife 002 phase 2b/3 trial is expected to commence in Israel and the Nation of Georgia, with European and North American countries to be added once the initial phase 2b volunteers have been vaccinated. The trial configuration will be a non-inferiority design comparing BriLife to an already approved vaccine. Interest from potential national participants in the trial design has been elevated by recently-released early data suggesting that BriLife has the potential to generate antibody responses to the Delta variant of the Coronavirus. Laboratory studies of antibody response to the Omicron variant are underway.

In contrast to first-generation vaccines against COVID, BriLife is a viral vector vaccine that presents the entire spike protein complex of the Coronavirus to the body's immune system and is able to present multiple variants of the spike protein simultaneously. NRx believes that this will potentially equip BriLife to create a more robust immune response than vaccines that present only a single variant of the spike protein or even a portion of a single variant to the immune system.

Unlike other vaccines, BriLife binds to the specific cells in the lung and nasal cavity that are targeted by the Coronavirus. This creates a potential for the vaccine to create a level of tissue immunity that may prevent vaccinated individuals from contracting and spreading new variants of COVID, even if they do not personally contract the virus. The binding of BriLife to cells that line the respiratory tract similarly open the possibility of delivering the vaccine as a nasal spray.

"We are excited to move forward with a multi-nation trial of BriLife at a time when the immunity that has been built through widespread adoption of first-generation vaccines is increasingly challenged by new variants," said Prof. Jonathan Javitt, MD, MPH, Chairman and CEO of NRx Pharmaceuticals.

About NRx Pharmaceuticals

NRx Pharmaceuticals (NRx) draws upon more than 300 years of collective, scientific, and drug-development experience to bring improved health to patients. 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 continues to develop, ZYESAMI® (aviptadil) for patients with COVID-19, which 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 (BARDA) 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 Prof Jonathan Javitt, MD, MPH, who has held leadership roles in medical technology 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 US 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.

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Source: NRx Pharmaceuticals, Inc.

Released December 6, 2021

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