NRx Announces Planned Study Investigating BriLife™ Booster Vaccine Against Omicron Variant

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•Trial targeted to begin in the first quarter of 2022
•NRx is coordinating study with the US Health and Human Services Biomedical Advanced Research and Development Authority and several European Governments
•Israel Ministry of Health has approved first-in-human trial of intradermal BriLife vaccination with the objective of enhancing immune response
•NRx continues technology transfer and scale up activities in anticipation of GMP manufacture

RADNOR, Pa., Jan. 11, 2022 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals (NASDAQ: NRXP), a clinical-stage, biopharmaceutical company, expanded on the information provided Monday at the H.C. Wainwright BioConnect Virtual Conference regarding the BriLife™ investigational vaccine for COVID-19.

Last week, NRx met with experts from the Israel Institute for Biological Research (IIBR) to review data and research related to the ability of the BriLife vaccine to induce neutralizing antibodies against the Omicron variant. Based on the preliminary findings, NRx is currently designing a phase 2b/3 study of the BriLife vaccine as a booster to protect against COVID-19 variants of concern including the Omicron variant. Patients in the study will be fully vaccinated with mRNA vaccines. It is anticipated that the study will begin in the first quarter of 2022 in Israel and will be expanded in coordination with the health ministries of several countries. The IIBR previously published initial serological findings documenting a neutralizing antibody response against the Delta variant that was comparable to the response against the wild-type SARS-CoV-2 virus. (JAFFE-HOFFMAN, 2021)

“We have seen the deadly impact caused by COVID-19 and its increasing number of variants, and we are eager to determine the immunity-building impact the BriLife vaccine may offer on top of that already conferred by baseline mRNA vaccination,” said Prof Jonathan Javitt, MD, MPH, Chairman and CEO of NRx Pharmaceuticals. “We are working closely with the experts at the IIBR to design a study that we hope increases BriLife’s accelerated path to regulatory approval.”

NRx was contacted in late December by representatives of the US Department of Health and Human Services and several European Governments with a request to present Omicron findings.

In further news, the Israel Ministry of Health recently approved a study investigating the NanoPass MicronJet™ intradermal injection system for the BriLife vaccine. The NanoPass system, invented in Israel, uses a patented microneedle system to deliver the vaccine into the skin with minimal discomfort.

This approach is especially promising for the BriLife vaccine because it binds to angiotensin-converting enzyme 2 (ACE2) receptors, which are present in significantly larger quantities in human skin cells than in muscle cells where traditional vaccines are injected. In addition, early data with other vaccines suggests that intradermal delivery of BriLife may result in a more robust immune response at substantially lower vaccine dosing.

As these studies are moving towards initiation, NRx continues technology transfer and scale-up activities in anticipation of commercial scale manufacture by Q4 2022.

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. The Company is developing the BriLife™ Covid vaccine, developed by the Israel Institute for Biological Research, under an exclusive license from the Israel Ministry of Defense. NRx is additionally developing ZYESAMI® (aviptadil) for patients with COVID-19, and 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 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 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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