



NRx Pharmaceuticals and Hungarian Health Officials Agree on Pathway for ZYESAMI® and BriLife COVID-19 Vaccine Trials

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- NRx and Hungary Agree on Regulatory Path for Emergency Use of ZYESAMI
- Hungary to Serve as First European Nation for the Registrational Phase 2b/3 BriLife COVID Vaccine Trial

BUDAPEST, Hungary, Dec. 09, 2021 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals (NASDAQ: [NRXP](#)) today announced the conclusion of high-level meetings in Hungary that are expected to lead to utilization of ZYESAMI® (aviptadil) in that country and the pivotal clinical trial of the BriLife COVID-19 vaccine (BriLife).

Hungary will be the first European Nation to host a clinical trial site for the registrational phase 2b/3 trial of the BriLife COVID-19 vaccine. In addition to the already-developed trial protocol, NRx has been invited to submit a pediatric trial protocol that may include both injected and nasal spray administration of the vaccine. The NRx initiative in Hungary will be led by senior regulatory and academic medical leaders. Regulatory clearance for the BriLife trial is expected by the end of 2021.

Hungarian health officials have also agreed on a regulatory path for Emergency Use of ZYESAMI® (aviptadil) in the Central European region, which will start with a compassionate care program expected to begin by the end of 2021. The program is modeled on the US Food and Drug Administration's approved Expanded Access Protocol already implemented in the United States. Confirmatory demonstration of clinical effect under this program will be submitted with safety and efficacy data in support of Emergency Use Authorization in Hungary. Europe, like much of the world, is experiencing a resurgence of COVID-19, with more than 15,000 people currently infected and more than 200 people dying in Hungary each day.



"NRx is pleased to partner with Hungary to bring two lifesaving therapies, ZYESAMI and the BriLife COVID-19 vaccine, to people in the Central European region at a time when humanity's war against COVID is far from over," said Prof Jonathan Javitt, MD, MPH Chairman and CEO of NRx. "We are pleased to have a positive and patient-centric working relationship with Hungarian health authorities that we believe will help prevent COVID-19 infection and serve patients who have exhausted all other approved treatments."

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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