NeuroRx and Relief Therapeutics Announce Data Monitoring Committee Determination to Continue Phase 2/3 Trial of RLF-100 for Critical COVID-19

July 16, 2020

•With resurgent COVID-19, enrollment has accelerated in Miami, Houston, and Irvine

•Data Monitoring Committee determined that so far RLF-100 has generated no drug-related Serious Adverse Events or other safety concerns that would mandate stopping. The study is to continue until the next scheduled data review in four weeks.

•Primary endpoint is established as "Alive and free of Respiratory Failure at 7-10 days"

RADNOR, Pa. and GENEVA, July 16, 2020 (GLOBE NEWSWIRE) -- NeuroRx, Inc., in partnership with RELIEF THERAPEUTICS Holdings AG (SIX:RLF, OTC:RLFTF) today announced that the independent Data Monitoring Committee has reviewed the findings in the first 30 patients treated in Fast Track FDA trials of RLF-100 (Aviptadil) in patients with Critical COVID-19 with respiratory failure.

The study protocol enrolls patients with Critical COVID-19 and Respiratory Failure and randomly assigns them to intravenous RLF-100 or Placebo in the hopes of achieving remission from this most-serious stage of COVID-19. At the committee's recommendation, the primary endpoint is changed to "alive and free of respiratory failure at 7-10 days." This change in primary endpoint from mortality at 28 days is driven by the general decrease in mortality with advances in treatment for Critical COVID-19 and by initial observations in the clinical trial.

This first interim analysis was focused on verifying the apparent safety of the drug in the first 30 patients and the feasibility of the study to reach its endpoint. The committee determined that the study appeared capable of reaching a statistically significant endpoint within its 144 patient sample size and voted for the study to continue until its next scheduled evaluation in four weeks.

The committee is composed of Prof. Alfred Sommer, MD, MHS, Dean Emeritus of the Johns Hopkins Bloomberg School of Public Health, Prof. Rita Colwell, PhD, former Director of the National Science Foundation, and Congressman Andy Harris, MD, MHS (MD District 1) a part time Professor of Anesthesia and Critical Care at Johns Hopkins School of Medicine.

RLF-100 (Aviptadil) received Fast Track designation from the US FDA for the treatment of Critical COVID-19 with respiratory failure. RLF-100 is a synthetic form of human Vasoactive Intestinal Peptide (VIP) which is known to protect the Alveolar Type II cell of the lung from many forms of injury. This cell is critical to transmission of oxygen to the blood and is the site of attack for the Coronavirus.

"This milestone represents the extraordinary effort of our partners and collaborators at the University of Miami, Houston Methodist Hospital, UC Irvine, and the University of Louisville who gave 100% to providing patients with Critical COVID-19 a chance to benefit from a potentially life-saving drug. We thank the members of the Data Monitoring Committee for devoting their valuable time to performing this vital role in helping to evaluate the safety and effectiveness of RLF-100," said Prof. Jonathan C Javitt, MD, MPH, CEO of NeuroRx and the National Study Chair.

Details of the study are posted on clinicaltrials.gov NCT04311697.

About RLF-100

RLF-100 (Aviptadil) is a patented formulation of Vasoactive Intestinal Polypeptide (VIP) that was developed based on Dr. Said's original work and was originally approved for human trials by the FDA in 2001 and the European Medicines Agency in 2005. VIP is primarily concentrated in the lung and is known to protect against a variety of lung injuries. VIP was awarded Orphan Drug Designation in 2001 by the U.S. FDA for treatment of Acute Respiratory Distress Syndrome and in 2005 for treatment of Pulmonary Arterial Hypertension. The European Medicines Agency awarded orphan drug designation in 2006 for the treatment of acute lung injury and in 2007 for the treatment of sarcoidosis.

About RELIEF THERAPEUTICS Holding AG

The Relief group of companies focus primarily on clinical-stage projects based on molecules of natural origin (peptides and proteins) with a history of clinical testing and use in human patients or a strong scientific rationale. Currently, Relief is concentrating its efforts on developing new treatments for respiratory disease indications.

Relief Therapeutics holds orphan drug designations from the U.S. Food and Drug Administration and the European Union for the use of VIP to treat ARDS, pulmonary hypertension, and sarcoidosis. Relief Therapeutics also holds a U.S. patent1 for RLF-100

and proprietary manufacturing processes for its synthesis.
RELIEF THERAPEUTICS Holding AG is listed on the SIX Swiss Exchange under the symbol RLF.

About NeuroRx, Inc.

NeuroRx draws upon more than 100 years of collective drug development experience and is led by former senior executives of Johnson & Johnson, Eli Lilly, Pfizer, and AstraZeneca, PPD. In addition to its work on RLF-100, NeuroRx has been awarded Breakthrough Therapy Designation and a Special Protocol Agreement to develop NRX-101 for the treatment of suicidal bipolar depression and is currently in Phase 3 trials. Its Board of Directors and Advisors includes Hon. Sherry Glied, former Assistant Secretary, U.S. Dept. of Health and Human Services; Mr. Chaim Hurvitz, former President of the Teva International Group, Lt. Gen. HR McMaster, the 23rd National Security Advisor, Wayne Pines, former Associate Commissioner of the U.S. Food and Drug Administration, Judge Abraham Sofaer, and Daniel Troy, former Chief Counsel, U.S. Food and Drug Administration.

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1 US 8,178,489 Formulation for Aviptadil

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