NeuroRx and Relief Therapeutics announce continuation of RLF-100™ trial for treatment of COVID-19 Respiratory Failure: Trial is on track to complete enrollment in 2020

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RADNOR, Pa. and GENEVA, Nov. 5, 2020 /PRNewswire/ -- NeuroRx, Inc. and Relief Therapeutics Holdings AG (SIX:RLF, OTCBB:RLFTF) ("Relief") announced that the independent Data Monitoring Committee (DMC) met yesterday and voted unanimously that NCT 04311697 should continue as planned to its full enrollment of 165 patients. Specifically, the committee identified no safety concerns and viewed the study as capable of reaching its prespecified endpoint (i.e. no finding of futility) in potentially proving that RLF-100™ (aviptadil) is superior to placebo in achieving recovery from Respiratory Failure in patients with Critical COVID-19 at a statistically significant level.

RLF-100™ was granted FDA Fast Track designation in June 2020 and was previously granted Orphan Drug Designation for the treatment of Acute Respiratory Distress Syndrome. In an earlier, open label study of patients with severe comorbidities that disqualified them from the randomized prospective trial, a statistically-significant (P<.0001) benefit in both recovery from respiratory failure and in survival was seen compared to control patients who received Standard of Care treatment (http://dx.doi.org/10.2139/ssrn.3665228).

The review by the DMC was based on data from 102 patients who were randomly assigned to intravenous RLF-100™ vs. placebo and who have completed 28 days or more of observation. All patients were hospitalized in intensive care units with respiratory failure treated by mechanical ventilation, non-invasive ventilation, or high-flow nasal oxygen. So far, 133 patients have been treated in this protocol. At current rates of enrollment (which may change as infection rates change) the study is expected to complete enrollment by mid-December and yield top-line data in January 2021.

Although the study remains blinded, the randomized data overall show that there have been no drug-related Serious Adverse Events to date. Similarly, no drug-related adverse events were seen in either the open label study of the ongoing Expanded Access Protocol.

In contrast to other recently-reported trials, the RLF-100™ phase 2b/3 trial focuses on patients with Critical COVID-19 who already require intensive care for Respiratory Failure. Currently, there is no approved drug that has shown efficacy in this population, nor are there late stage trials of other experimental therapeutics focusing on these patients.

The seven-person DMC included two independent biostatisticians, an epidemiologist/clinical trials expert, a bioethicist, a public representative, and clinical experts in pulmonary and critical care medicine.

About VIP in Lung Injury

Vasoactive Intestinal Polypeptide (VIP) was first discovered by the late Dr. Sami Said in 1970. Although first identified in the intestinal tract, VIP is now known to be produced throughout the body and to be primarily concentrated in the lungs. VIP has been shown in more than 100 peer-reviewed studies to have potent anti-inflammatory/anti-cytokine activity in animal models of respiratory distress, acute lung injury, and inflammation. Most importantly, 70% of the VIP in the body is bound to a rare cell in the lung, the alveolar type 2 cell, that is critical to transmission of oxygen to the body. VIP has a 20-year history of safe use in humans in multiple human trials for sarcoidosis, pulmonary fibrosis, asthma/allergy, and pulmonary hypertension.

COVID-19-related death is primarily caused by respiratory failure. Before this acute phase, however, there is evidence of early viral infection of the alveolar type 2 cells. These cells are known to have angiotensin converting enzyme 2 (ACE2) receptors at high levels, which serve as the route of entry for the SARS-CoV-2 into the cells. Coronaviruses are shown to replicate in alveolar type 2 cells but not in the more numerous type 1 cells. These same type 2 alveolar cells have high concentrations of VIP receptors on their cell surfaces giving rise to the hypothesis that VIP could specifically protect these cells from injury.

Injury to the type 2 alveolar cells is an increasingly plausible mechanism of COVID-19 disease progression (Mason 2020). These specialized cells replenish the more common type 1 cells that line the lungs. More importantly, type 2 cells manufacture surfactant that coats the lung and are essential for oxygen exchange. Other than RLF-100™, no currently proposed treatments for COVID-19 specifically target these vulnerable type 2 cells.

About RLF-100™

RLF-100™ (Aviptadil) is a formulation of Vasoactive Intestinal Polypeptide (VIP) that was developed based on Prof.. Sami Said's original work at Stony Brook University, for which Stony Brook was awarded an FDA Orphan Drug Designation in 2001. VIP is

known to be highly concentrated in the lungs, where it inhibits coronavirus replication, blocks the formation of inflammatory cytokines, prevents cell death, and upregulates the production of surfactant. FDA has now granted IND authorization for intravenous and inhaled delivery of RLF-100™ for the treatment of COVID-19 and awarded Fast Track designation. RLF-100™ is being investigated in two placebo-controlled US Phase 2b/3 clinical trials in respiratory deficiency due to COVID-19. Since July 2020, more than 150 patients with Critical COVID-19 and Respiratory Failure have been treated with RLF-100™ under FDA-approved protocols. Information on the RLF-100™ Expanded Access program is at https://www.neurorxpharma.com/our-services/rlf-100.

About RELIEF THERAPEUTICS Holding AG

Relief focuses primarily on clinical-stage programs 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 holds orphan drug designations from the U.S. FDA and the European Union for the use of VIP to treat ARDS, pulmonary hypertension, and sarcoidosis. Relief also holds a patent issued in the U.S. and multiple other countries covering potential formulations of RLF-100™.

RELIEF THERAPEUTICS Holding AG is listed on the SIX Swiss Exchange under the symbol RLF and quoted in the U.S. on the OTCQB under the symbol RLFTF.

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 in suicidal bipolar depression and is currently in Phase 3 trials. Its executive team is led by Prof. Jonathan C. Javitt, MD, MPH, who has served as a health advisor to four Presidential administrations and worked on paradigm-changing drug development projects for Merck, Allergan, Pharmacia, Pfizer, Novartis, and Mannkind, together with Robert Besthof, MIM, who served as the Global Vice President (Commercial) for Pfizer's Neuroscience and Pain Division. 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.

Disclaimer: This communication expressly or implicitly contains certain forward-looking statements concerning RELIEF THERAPEUTICS Holding AG, NeuroRx, Inc. and their businesses. The results reported herein may or may not be indicative of the results of future and larger clinical trials for RLF-100™ for the treatment of COVID-19. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of RELIEF THERAPEUTICS Holding AG and/or NeuroRx, Inc. to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. RELIEF THERAPEUTICS Holding AG is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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