



NeuroRx, Relief, and Quantum Leap announce the inclusion of ZYESAMI™ (RLF-100™: aviptadil) in the I-SPY COVID-19 Trial

RADNOR, Pa. and GENEVA, Jan. 11, 2021 [/PRNewswire/](#) -- NeuroRx, Inc. and RELIEF THERAPEUTICS Holding AG (SIX: RLF, OTCQB: RLTF) ("Relief"), and the Quantum Leap Healthcare Collaborative ("Quantum Leap") of San Francisco announce that NeuroRx and QLHC have signed a Clinical Trial Participation Agreement for the inclusion of ZYESAMI™ (RLF-100™: aviptadil) in the I-SPY COVID-19 Clinical Trial. Quantum Leap is the sponsor of the I-SPY COVID-19 Trial, a platform trial that is assessing multiple drugs for the treatment of patients with Critical COVID-19 who are hospitalized or in intensive care units. ZYESAMI™ will be included as one of the first drugs targeting Respiratory Failure in critically ill COVID-19 patients.

The inclusion of ZYESAMI™ in the I-SPY COVID-19 Trial follows a request from the U.S. Department of Health and Human Services and the Department of Defense for investigational drugs capable of targeting the most acutely ill patients with COVID-19. ZYESAMI™ has been granted Fast Track designation by the U.S. Food & Drug Administration (FDA) for the treatment of Critical COVID-19 in patients with Respiratory Failure.

In December 2020, Dr. Robert Kadlec, HHS Assistant Secretary for Preparedness and Response, issued a public statement that "Through our Operation Warp Speed partnership, we have worked feverishly with private industry to develop and make treatments available to reduce hospitalization, either shortening the length of stay or treating people with mild or moderate COVID-19 infections before they have to be hospitalized. While we're making significant progress, treatments to save lives of the sickest patients, such as patients in intensive care or on ventilators, remain an urgent need."

I-SPY is a platform clinical trial that uses a similar protocol as a traditional clinical trial, but that compares multiple investigational agents combined with a "backbone" of the standard of care. The trial is designed to rapidly identify those agents that have a large impact on reducing disease severity, including reduced mortality, reducing or avoiding time on ventilation and other longer-term comorbidities. Patients receive one of several products being studied and the results then are compared to the current standard of care.

"We are excited to be collaborating with NeuroRx, an innovative company developing agents that have the potential to significantly impact the time to recovery and mortality in these severely ill COVID-19 patients," states Dr. Laura Esserman, one of the lead investigators of the I-SPY COVID-19 Trial. "Our adaptive platform trial setting is the ideal type of study to follow a trial that has findings suggesting agent effectiveness. We have the ability to independently verify impact, as well as test different modes of delivery in a pandemic timeframe."

"We at NeuroRx, together with our partners at Relief, are honored to have been selected by Quantum Leap for inclusion in the I-SPY trials platform. This will enable us to gather data on the use of inhaled aviptadil in the treatment of Critical COVID-19, as a complement to data on the use of intravenous aviptadil in the phase 2b/3 trial we are just concluding. We also hope to demonstrate in a second phase 2b/3 trial that aviptadil can be given in a more convenient mode of administration and show benefit in patients who are able to self-administer inhaled medications," said Jonathan C. Javitt, MD, MPH, CEO and Chairman of NeuroRx.

About ZYESAMI™ (RLF-100™: aviptadil)

ZYESAMI™ (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 granted IND authorization for intravenous and inhaled delivery of aviptadil for the treatment of COVID-19 and awarded Fast Track designation. ZYESAMI™ 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 300 patients with Critical COVID-19 and Respiratory Failure have been treated with RLF-100™ between the two FDA-cleared protocols (randomized and expanded access). Information on the RLF-100™ Expanded Access Program can be found at <https://www.neurorxpharma.com/our-services/rlf-100>.

About NeuroRx, Inc.

NeuroRx draws upon more than 100 years of collective drug development experience and by former senior executives of AstraZeneca, Eli Lilly, Novartis, Pfizer, and PPD. In addition to its work on ZYESAMI™, which has been awarded FDA Fast Track designation (previously RLF-100™: Aviptadil), 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. The Company has recently announced a plan to merge with Big Rock Partners Acquisition Corp (NASDAQ:BRPA) ("Big Rock"), following which it is expected to trade on the NASDAQ as NRXP.

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. Its lead drug candidate RLF-100™ (aviptadil) is being investigated in two placebo-controlled U.S. phase 2b/3 clinical trials in respiratory deficiency due to COVID-19. Relief also holds a patent issued in the United States and various 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 OTCQB under the symbol RLTF.

www.relieftherapeutics.com

About Quantum Leap Healthcare Collaborative

Quantum Leap Healthcare Collaborative is a 501(c)(3) charitable organization established in 2005 as a collaboration between medical researchers at University of California, San Francisco, academic medical sites and clinical researchers (nationwide), the pharma industry and healthcare technology leaders. Its mission is to integrate high-impact research with clinical processes and systems technology, resulting in improved data management and information systems, greater access to clinical trial matching and sponsorship, and greater benefit to providers, patients and researchers. Its goal is to improve and save lives. Quantum Leap provides sponsorship as well as operational, financial, and regulatory oversight to the I-SPY Trials. For more information, visit www.QuantumLeapHealth.org.

About Big Rock Partners Acquisition Corp.

Big Rock Partners Acquisition Corp. is a blank check company formed for the purpose of entering into a merger, stock exchange, asset acquisition, stock purchase, recapitalization, reorganization, or other similar business

combination with one or more businesses or entities. Big Rock's management team includes Richard Ackerman, Chairman, President, and Chief Executive Officer, and Bennett Kim, Chief Financial Officer, Chief Investment Officer, Corporate Secretary and Director. Big Rock's common stock, units, rights and warrants are quoted on the Nasdaq Capital Market under the ticker symbols BRPA, BRPAU, BRPAR and BRPAW, respectively.

Additional Information and Where to Find It

This document relates to a proposed transaction between NeuroRx and Big Rock. This document does not constitute an offer to sell or exchange, or the solicitation of an offer to buy or exchange, any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, sale or exchange would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. Big Rock intends to file a registration statement on Form S-4 ("Registration Statement"), which will include a proxy statement for the solicitation of Big Rock shareholder approval, a prospectus for the offer and sale of Big Rock securities in the transaction and a consent solicitation statement of NeuroRx, and other relevant documents with the Securities and Exchange Commission ("SEC"). The proxy statement/consent solicitation statement/prospectus will be mailed to stockholders of Big Rock and NeuroRx as of a record date to be established for voting on the proposed business combination. INVESTORS AND SECURITY HOLDERS OF BIG ROCK AND NEURORX ARE URGED TO READ THE REGISTRATION STATEMENT, PROXY STATEMENT/CONSENT SOLICITATION STATEMENT/PROSPECTUS AND OTHER RELEVANT DOCUMENTS THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders will be able to obtain free copies of the registration statement, proxy statement, prospectus and other documents containing important information about Big Rock and NeuroRx once such documents are filed with the SEC, through the website maintained by the SEC at <http://www.sec.gov>.

Additional Information Posted to Website

Big Rock will post information regarding the proposed transaction promptly at www.bigrockpartners.com. An investor presentation has been furnished by Big Rock to the SEC on a current report on Form 8-K, which can be viewed at the SEC's website at www.sec.gov and www.bigrockpartners.com. Big Rock intends to use its website as additional means of disclosing information to investors, the media, and others interested in Big Rock. It is possible that certain information that Big Rock posts to its website could be deemed material information, and Big Rock encourages investors, the media, and others interested in Big Rock to review the business and financial information that Big Rock posts on its website as such information could be deemed to be material information.

Participants in the Solicitation

Big Rock, NeuroRx and EarlyBirdCapital and their respective directors and executive officers, under SEC rules, may be deemed to be participants in the solicitation of proxies of Big Rock's shareholders in connection with the proposed transaction. Investors and securityholders may obtain more detailed information regarding the names and interests in the proposed transaction of Big Rock's directors and officers in Big Rock's filings with the SEC, including the forthcoming proxy statement/consent solicitation statement/prospectus statement. You may obtain a free copy of these documents as described in the preceding paragraph.

No Offer or Solicitation

This communication shall neither constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which the offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction.

Cautionary Note Regarding Forward Looking Statements

Neither Big Rock, NeuroRx nor any of their respective affiliates makes any representation or warranty as to the accuracy or completeness of the information contained in this press release. This press release is not intended to be all-inclusive or to contain all the information that a person may desire in considering the proposed

transaction discussed herein. It is not intended to form the basis of any investment decision or any other decision in respect of the proposed transaction.

This press release includes "forward-looking statements" within the meaning of the federal securities laws with respect to the proposed transaction between NeuroRx, Inc. and Big Rock, including statements regarding the benefits of the transaction, the anticipated timing of the transaction, the drugs under development by NeuroRx and the markets in which it operates. Big Rock's and NeuroRx's actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements generally are identified by the words "aspire," "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "will be," "will continue," "will likely result," "could," "should," "believe(s)," "predicts," "potential," "continue," "future," "opportunity," "strategy," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, Big Rock's and NeuroRx's expectations with respect to future performance and anticipated financial impacts of the proposed transaction.

These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside Big Rock's and NeuroRx's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: (1) the approvals, timing, and ability to complete the proposed business combination, which may adversely affect the trading price of Big Rock's securities; (2) Big Rock's ability to remain listed on the Nasdaq Capital Market prior to the closing of the proposed business combination; (3) the combined company's continued listing on the NASDAQ Capital Market after closing of the proposed business combination; (4) the benefits of the proposed business combination, including future financial and operating results of the combined company; (5) the inherent uncertainty associated with the FDA approval process; (6) the risk that the proposed transaction disrupts current plans and operations of NeuroRx as a result of the announcement and consummation of the transaction described therein and herein; (7) costs related to the proposed business combination; (8) changes in applicable laws or regulations; (9) the possibility that the combined company may be adversely affected by other economic, business, and/or competitive factors; (10) the impact of COVID-19 or other adverse public health developments; and (11) other risks and uncertainties that will be detailed in the proxy statement/consent solicitation statement/prospectus and registration statement to be filed on Form S-4 with the SEC and as indicated from time to time in Big Rock's filings with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

Big Rock and NeuroRx caution that the foregoing list of factors is not exclusive. Big Rock and NeuroRx caution readers not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Neither Big Rock nor NeuroRx undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

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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SOURCE NeuroRx

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