

## NRx Pharmaceuticals Files Counterclaim Against its Former Collaboration Partner, Relief Therapeutics

- Documents NRx's development of a potentially lifesaving drug for treatment of Covid-19 despite Relief's breach and repudiation of the collaboration agreement

- Details Relief's false claims of worldwide rights to Aviptadil and to ongoing phase 3 research, misleading NRx and the public

- Identifies Raghuram Selvaraju's history of collaborating with Relief principals and associates on prior matters that have led to sanctions, fines, and incarceration

- Documents Relief's attempt to extort NRx into using Relief's ineffective and potentially harmful formulation of Aviptadil

- Debunks the libelous claim that NRx caused harm to patients in Europe by withholding patient data

RADNOR, Pa., Jan. 12, 2022 /<u>PRNewswire</u>/ -- NRx Pharmaceuticals (Nasdaq: NRXP) filed a lawsuit on Monday against Relief Therapeutics (SIX: RLF, OTCQB: RLFTF, RLFTY), its former collaboration partner, in New York State Supreme Court. <u>https://iapps.courts.state.ny.us/fbem/DocumentDisplayServlet?</u>

<u>documentId=Kq2Z2hThuv/7j5mV5Q4PYw==&system=prod</u> The counterclaim details Relief's breach and repudiation of the collaboration agreement, highlights the false nature of Relief's claims to have worldwide rights to Aviptadil, to have engaged in phase 3 research using Aviptadil, and to having any human grade drug available to treat patients. The lawsuit details a past pattern of collusion by Raghuram Selvaraju and members of Relief's management and associates in matters that have led to criminal investigations, sanctions, fines, and in one case incarceration. NRx seeks \$185 million in reliance damages as well further punitive damages associated with the libelous and extortionate behavior.

NRx regrets Relief's decision to delay the scheduled December mediation to late February and looks forward to resolving this dispute with Relief as soon as possible. Notwithstanding, NRx advised Relief today that the collaboration agreement is no longer in effect, given Relief's breach and repudiation of the agreement. NRx advised Relief's leadership to cease misrepresenting itself as NRx's collaboration partner in communications such as those offered at this week's H.C Wainwright BioConnect Virtual Healthcare Conference and in recent filings before the US Securities and Exchange Commission. NRx believes that it is the shareholders of Relief and the patients in Europe who need access to this medicine who are the primary victims of Relief's claims to have a drug (which they call RLF-100) to offer patients. From NRx's perspective, the chief priority should be saving lives in the middle of a public health emergency.

"Now that our counterclaim is filed, we hope to get back to the business of saving lives. The phase 3 trial sponsored by the National Institutes of Health has enrolled more than two-thirds of its participants and is now starting its international phase. We have just submitted data to the FDA documenting that patients treated with ZYESAMI (Aviptadil) after failing to recover on remdesivir have a 3-fold increased odds of recovery from the ICU, compared to those treated with placebo and a 4-fold increased odds of surviving to day 60," said Prof Jonathan Javitt, MD, MPH, Chairman and CEO of NRx. "Just last weekend, we were involved in airlifting our medication under the Federal Right to Try Act to the bedside of a patient in Washington, D.C. who is turning the corner as we speak. Last week, Dr. Jacobo Elgozy published his first-person experience of a last-minute recovery in a Miami

Newspaper. <u>https://miamicourant.com/stories/617928153-op-ed-the-emergency-use-law-should-be-used-for-emergencies-like-now</u> Also last week, we received a report from a small hospital in Texas where 17 of 19 patients treated with our drug under the Right to Try program survived and returned to their families.

It's this mission on saving lives that keeps us going 24/7 and drives us as a company. We continue to pursue regulatory clearance to distribute ZYESAMI under Right to Try laws. We look forward to restarting enrollment next month for our breakthrough drug, NRX-101, for suicidal bipolar depression, particularly since suicide rates have doubled with the stress of the public health emergency. As we shared earlier this week, we look forward to starting a trial of the BriLife vaccine as a booster injection to prevent some of the variants that have circumvented the mRNA vaccines."

NRx regrets the necessity of terminating the collaboration agreement and answering our former collaboration partner in court in order to expose the true nature of its management's actions. Relief callously breached its contract obligations by failing to fund the research and clinical trials as obligated. Relief has continued to mislead the public and shareholders by claiming, via Mr. Jack Weinstein's presentation at this week's H.C. Wainwright BioConnect Virtual Healthcare Conference, ownership over NRx's expanded access programs, participation in the NIH clinical trials, and development of commercial scale manufacturing and distribution programs undertaken solely by NRx that Relief refused to fund and in which Relief did not participate.

The myriad of facts in the counterclaim paint a picture of Relief's management refusing to fulfill its commitments under the collaboration agreement, the main purpose of which was to develop and trial a potentially lifesaving treatment for Covid-19. This behavior is not only a contractual breach but is shameful. The counterclaim spells this out in great detail. The unique circumstances of this case underscore why we chose to be represented by a former United States Federal prosecutor and an attorney who has been effective in prosecuting malicious foreign enterprises.

While we at NRx are confident that we will prevail against our former collaboration partner, we are deeply offended by the baseless and libelous accusation of Relief's management that we somehow harmed patients in Europe by withholding clinical data required for its regulatory submission. The simple fact is that Relief never manufactured a drug to distribute to patients and attacked us in order to obscure that deception. The written record shows that we offered Relief our full cooperation despite its breach of contract and even offered to manufacture ZYESAMI to European standards for Relief, only to be rebuffed and ultimately sued. Certainly, nobody has benefited from this behavior on the part of our former collaboration partner, least of all patients in Europe and the United Kingdom.

NRx has now manufactured ZYESAMI according to the Good Manufacturing Practices required by the European Union and the United Kingdom and has retained regulatory counsel in both jurisdictions to make actual drug product immediately pending regulatory approval. Dr. Francis Collins, formerly of the National Institutes for Allergy and Infectious Diseases (NIAID) recently identified ZYESAMI as one of the few drugs still under study for the very sickest patients with COVID-19, those in the ICU on ventilators. We have recently reported to the FDA an observed 10-fold increase in odds of survival among patients who remain at risk of death despite treatment with remdesivir and other approved therapies.

We are similarly horrified that Relief's management attempted to coerce NRx into using Relief's patented formulation of aviptadil in critically-ill patients despite Relief's knowledge that the formulation was ineffective because the peptide aggregates and becomes denatured (much like frying an egg). Even though Relief knew its formulation had failed in clinical trials more than 10 years ago, Dr. Selvaraju demanded that NRx use this formulation in order to maintain the charade that Relief had worldwide patent rights. Relief's complaint that began this litigation alleges that we somehow harmed Relief by refusing to use this ineffective formulation, despite repeated written warnings to both NRx and Relief from Relief's former Chief Medical Officer and the inventor on their patent.

We are confident that the New York State Supreme Court will mete out the penalty merited by this offensive

behavior. In fact, we believe Relief's conduct is so egregious as to warrant the imposition of punitive damages. Under the law, punitive damages may be awarded when reprehensible and malicious conduct is directed not only at the plaintiff but at the public. NRx intends to donate any punitive damages awarded by the Court to assist COVID survivors, as they are the true victims of Relief's actions.

## 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 Planning and Evaluation (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.

## About ZYESAMI® (aviptadil)

Aviptadil is a synthetic form of Vasoactive Intestinal Polypeptide (VIP) first discovered by the late Prof. Sami Said in 1970, and ZYESAMI® is named in his honor. Although primarily concentrated in the lung, it was first purified from the intestinal tract. VIP binds specifically to the alveolar type II cell (ATII) in the air sac (alveolus) of the lung, where it has been shown have potent anti-inflammatory/anti-cytokine activity in animal models of respiratory distress, acute lung injury, and inflammation. Most importantly, VIP stimulates ATII cells to make the surfactant that must coat the lining of the lungs in order for them to exchange oxygen with the blood. Loss of surfactant causes respiratory failure and alveolar collapse, which are hallmarks of COVID-19.

COVID-19-related respiratory failure is caused by selective infection of the ATII cell by the SARS-CoV-2 virus. The ATII cells are vulnerable because of their (ACE2) surface receptors, which serve as the route of entry for the virus. Coronavirus infection of the ATII cell shuts down surfactant production, triggers the formation of inflammatory cytokines, and causes cell death (cytopathy). VIP is shown to upregulate surfactant production, block Coronavirus replication in the ATII cell, block cytokine synthesis, and prevent viral-induced cell death (cytopathy). Other than ZYESAMI®, no currently proposed treatments for COVID-19 specifically target this mechanism of action.

## 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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