

Ad hoc announcement pursuant to Art. 53 LR

Relief Reports that its U.S. Collaboration Partner has Announced the U.S. Food and Drug Administration has Denied Breakthrough Designation for Aviptadil

Geneva, Switzerland, November 24, 2021 – RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLFTF, RLFTY) ("**Relief**"), a biopharmaceutical company seeking to provide patients therapeutic relief from serious diseases with high unmet need, reported today that the parent company of its collaboration partner, NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx"), has issued a CEO Update announcing that the U.S. Food and Drug Administration ("**FDA**") has denied Breakthrough Therapy Designation ("**BTD**") for aviptadil. NRx noted that BTD is not required for drug approval or emergency use authorization, but can afford faster review times, the ability to submit a rolling application, and dedicated FDA review personnel who may interact more frequently with the sponsor. Additionally, according to the CEO Update, the FDA has already granted priority and rolling review as part of the Fast Track Designation awarded in July 2020. Therefore, the denial does not impede NRx's ability to seek drug approval, although it does identify areas where NRx needs to seek better scientific alignment with the FDA. The related NRx CEO Update can be accessed through the following link.

ABOUT RELIEF

Relief focuses primarily on clinical-stage programs based on molecules with a history of clinical testing and use in human patients or a strong scientific rationale. Relief's lead drug candidate, RLF-100[™] (aviptadil), a synthetic form of Vasoactive Intestinal Peptide (VIP), is in late-stage clinical testing in the U.S. for the treatment of respiratory deficiency due to COVID-19. As part of its pipeline diversification strategy, in March 2021, Relief entered into a Collaboration and License Agreement with Acer Therapeutics for the worldwide development and commercialization of ACER-001. ACER-001 is a taste-masked and immediate release proprietary powder formulation of sodium phenylbutyrate (NaPB) for the treatment of Urea Cycle Disorders and Maple Syrup Urine Disease. In addition, Relief's recently completed acquisitions of APR Applied Pharma Research SA and AdVita Lifescience GmbH, bring to Relief a diverse pipeline of marketed and development-stage programs.

RELIEF THERAPEUTICS Holding SA is listed on the SIX Swiss Exchange under the symbol RLF and quoted in the U.S. on OTCQB under the symbol RLFTF. For more information, visit <u>www.relieftherapeutics.com</u>. Follow us on <u>LinkedIn</u>.



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Disclaimer: This communication expressly or implicitly contains certain forward-looking statements concerning RELIEF THERAPEUTICS Holding SA. Such statements involve certain known and unknown risks, uncertainties and other factors, including (i) whether aviptadil will ever be approved in the U.S., the U.K., or the E.U. for the treatment of respiratory failure in patients with COVID-19, and (ii) those risks discussed in RELIEF THERAPEUTICS Holding SA's press releases and filings with the SIX, which could cause the actual results, financial condition, performance or achievements of RELIEF THERAPEUTICS Holding SA to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. RELIEF THERAPEUTICS Holding SA 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.