

Ad hoc announcement pursuant to Art. 53 LR

Relief Therapeutics Announces Six-Month Stability Data on a New Formulation of RLF-100® (Aviptadil)

This new formulation may have important clinical uses for a variety of rare lung diseases

Geneva, Switzerland, November 7, 2022 – RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLTF, RLFTD) (“Relief”), a Swiss, commercial-stage biopharmaceutical company identifying, developing, and commercializing novel, patent protected products in selected specialty, rare and ultra-rare disease areas on a global basis, today announced promising six-month stability data on a new formulation of RLF-100® (aviptadil). The reported data demonstrated high purity levels at six months at all temperatures tested, including at refrigerated and room temperature environments. The results are consistent with those observed at the three-month time period. Based on these results, Relief has filed a new provisional patent application.

“The testing conducted to date has shown our novel RLF-100® formulation to be shelf-stable at temperatures suitable for shipping and long-term storage, a critical step towards commercialization,” stated Raghuram (Ram) Selvaraju, Ph.D., Chairman of the Board of Directors of Relief. “We believe that this new, stable formulation has significant clinical and commercial value, and may allow RLF-100® to be delivered via multiple routes of administration for treatment of several debilitating lung disease indications including pulmonary sarcoidosis, acute respiratory distress syndrome (“ARDS”), berylliosis and checkpoint inhibitor-induced pneumonitis (“CIP”), all of which Relief plans to pursue. As previously reported, we intend to initiate a Phase 2b dose ranging study in 54 patients with pulmonary sarcoidosis using inhaled RLF-100® administered over a 12-week period. A pre-IND meeting with the U.S. Food and Drug Administration (FDA) is planned to confirm the efficacy and safety endpoints as well as the proposed dosing regimen and, based on a positive outcome, the trial is expected to begin during 2023.”

ABOUT RLF-100®

RLF-100® (aviptadil) is a synthetic form of Vasoactive Intestinal Peptide (“VIP”) consisting of 28 amino acids, which was first discovered in 1970. Although initially identified in the intestinal tract, human VIP is known to be produced throughout the body and to be primarily concentrated in the lungs where it has shown a multimodal mechanism of action: specifically, a decrease of inflammatory cytokines release leading to prevention of cytokine storm syndrome and viral replication, an immunomodulating effect, vasodilating and broncho-dilating effects, and prevention of surfactant depletion. Seventy percent of VIP in the body is bound to a less common type of cell in the lung, the alveolar type 2 cell, which is critical to the transmission of oxygen to the body.

RLF-100 has a 20-year history of safe use in humans in multiple human trials for sarcoidosis, idiopathic pulmonary fibrosis, asthma, pulmonary arterial hypertension, and sepsis-induced acute respiratory distress syndrome. A combination of aviptadil with phentolamine is approved for the treatment of erectile dysfunction by intra-cavernous injections in countries outside the U.S.

RLF-100[®] is under development for certain acute and chronic lung diseases, including pulmonary sarcoidosis, for which it was granted an Orphan Drug Designation (“ODD”) by the FDA. RLF-100[®] is also being explored for treatment of checkpoint inhibitor-induced pneumonitis (“CIP”), an indication in which Relief received Swiss method-of-use patent protection related to the inhaled formulation of RLF-100[®] into at least 2039. RLF-100[®] will also be evaluated in treating non-COVID-19-related ARDS with a particular focus on infectious ARDS. There are also plans to conduct European proof-of-concept clinical development of RLF-100[®] in the treatment of chronic berylliosis, an orphan lung disease for which there are no treatments approved and which is characterized by severe inflammation of the lungs, coughing and increasing breathlessness (dyspnea).

ABOUT RELIEF

Relief is a Swiss, commercial-stage, biopharmaceutical company focused on identification, development and commercialization of novel, patent protected products intended for the treatment of rare and ultra-rare diseases including metabolic disorders, pulmonary diseases, and connective tissue disorders. Relief’s diversified pipeline consists of assets that have the potential to effectively address significant unmet medical needs, including PKU GOLIKE[®], engineered with the proprietary Physiomimic technology, which is the first prolonged-release amino acid product commercialized for the dietary management of phenylketonuria (“PKU”). Relief has a Collaboration and License Agreement with Acer Therapeutics for the worldwide development and commercialization of ACER-001 (sodium phenylbutyrate) for the treatment of various inborn errors of metabolism, including Urea Cycle Disorders (“UCDs”) and Maple Syrup Urine Disease (“MSUD”). Relief also continues to develop aviptadil for several rare pulmonary indications. Further, Relief is in clinical development for APR-TD011, a differentiated acid oxidizing solution of hypochlorous acid intended for the treatment of epidermolysis bullosa (“EB”), a group of rare, genetic, life-threatening connective tissue disorders; APR-TD011 has been granted Orphan Drug Designation by the FDA. Finally, Relief is commercializing several legacy products via licensing and distribution partners.

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 symbols RLTF and RLFTD.

For more information, visit www.relieftherapeutics.com. Follow Relief on [LinkedIn](#).

CONTACT:

RELIEF THERAPEUTICS Holding SA

Jack Weinstein
Chief Financial Officer and Treasurer
contact@relieftherapeutics.com

FOR MEDIA/INVESTOR INQUIRIES:

LifeSci Advisors

Irina Koffler
+1-917-734-7387
ikoffler@lifesciadvisors.com

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 the new formulation of RLF-100 will continue to be stable beyond six months, (ii) whether Relief's new provisional patent can be successfully prosecuted, (iii) whether Relief will be able to successfully start its Phase 2b dose ranging study in 2023 and whether that study will be successful, and (iv) those risks discussed in RELIEF THERAPEUTICS Holding SA's filings with the SIX and the U.S. Securities and Exchange Commission, 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.