## Ad hoc announcement pursuant to Art. 53 LR

# Relief Therapeutics Announces Promising Initial 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, August 3, 2022 –** RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLFTF, RLFTY) ("**Relief**"), a biopharmaceutical company seeking to provide patients therapeutic benefit from serious diseases with high unmet need, announced today promising three-month stability data on a new formulation of RLF-100® (aviptadil). Based on the results thus far, Relief is evaluating the opportunity to file for additional patent protection.

"Aviptadil, when dissolved in saline, is known to have uncertain stability properties, resulting in significant challenges for pharmaceutical supply and use. The development of this novel RLF-100® formulation, therefore, has significant clinical and commercial value. In particular, Relief's new formulation appears to be shelf-stable at temperatures suitable for shipping and long-term storage" stated Raghuram (Ram) Selvaraju, Ph.D., Chairman of the Board of Directors of Relief. "This new, stable formulation potentially allows RLF-100® to be delivered via multiple routes of administration for treatment of multiple lung disease indications including pulmonary sarcoidosis, acute respiratory distress syndrome (ARDS), berylliosis and checkpoint inhibitor-induced pneumonitis (CIP), all of which Relief seeks to pursue. As previously reported, we intend to initiate a phase 2b dose ranging study in 72 patients with pulmonary sarcoidosis using inhaled RLF-100® administered over a 12-week period, following which patients will have the option to participate in the extension phase. 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.

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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's wholly-owned subsidiary, AdVita LifeScience GmbH, 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 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 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 UCDs and Maple Syrup Urine Disease (MSUD). Relief also continues to study aviptadil for several possible lung related conditions. Finally, Relief's 2021 acquisitions of APR Applied Pharma Research SA and AdVita Lifescience GmbH brought 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 symbols RLFTF and RLFTY. For more information, visit www.relieftherapeutics.com. Follow Relief on **LinkedIn**.


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