Ad hoc announcement pursuant to Art. 53 LR

Relief Therapeutics Provides Update on Regulatory Interactions in the United Kingdom and European Union Relating to Lead Drug Candidate, RLF-100 (Aviptadil)

Geneva, Switzerland, September 13, 2021 – RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLFTF) ("**Relief**"), a biopharmaceutical company seeking to provide patients therapeutic relief from serious diseases with high unmet need, reported today that it has received scientific advice from the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) relating to its lead investigational drug, RLF-100™ (aviptadil), for the treatment of respiratory deficiency due to severe COVID-19. The guidance, which was provided in the context of a recent meeting that Relief held with the MHRA, included advice on the appropriate pathway for submission of an application for conditional marketing approval (CMA)[1] for the intravenous formulation of RLF-100, subject to provision of all data from the U.S. Phase 2b/3 study conducted by Relief's collaboration partner, NeuroRx, Inc. ("NeuroRx") According to the MHRA, a CMA through rolling review or expedited review process would be an appropriate pathway to ensure speedy access to beneficial treatments for patients infected with COVID-19. A rolling review allows the MHRA to start review of various sections of a submission as they are completed by Relief and provided to the MHRA.

Relief also reported today that it has held discussions with the European Medicines Agency (EMA) pertaining to the regulatory path forward for RLF-100 in the European Union. Relief has informed EMA that it will proceed with further dialogue with the MHRA once it has compiled critical information related to the study conduct, clinical data and the drug product.

Relief also reported that, to date, NeuroRx has not provided it with all of the data from its U.S. Phase 2b/3 study evaluating intravenously administered aviptadil for the treatment of respiratory failure in critically ill patients with COVID-19. There can be no assurance that NeuroRx will provide the required information.

[1] In the interest of public health, a CMA may be granted for medicines on less comprehensive clinical data than normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still required. Medicines for human use are eligible if they are intended for treating, preventing or diagnosing seriously debilitating or life-threatening diseases. This includes orphan medicines. Its use is also intended for a public health emergency (e.g., a pandemic).

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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 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 www.relieftherapeutics.com. Follow us on **LinkedIn**.

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