

Ad hoc announcement pursuant to Art. 53 LR

Relief Therapeutics Announces that its Collaboration Partner has Resubmitted the ACER-001 (sodium phenylbutyrate) New Drug Application (NDA) to the FDA for the treatment of urea cycle disorders (UCDs)

Geneva, Switzerland, July 18, 2022 – RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLFTF, RLFTY) (Relief), today announced that its collaboration partner, ACER Therapeutics, Inc. ("Acer"), for ACER-001 (sodium phenylbutyrate) for oral suspension for the treatment of patients with urea cycle disorders (UCDs), has resubmitted its New Drug Application (NDA) for ACER-001 to the U.S. Food and Drug Administration (FDA). Relief has been advised by Acer that it believes that the resubmission addresses, in full, the items raised by the FDA in the Complete Response Letter (CRL).

In June 2022, as previously announced, the FDA issued Acer a CRL stating that satisfactory inspection of its third-party contract packaging manufacturer is required before the ACER-001 NDA may be approved. Relief is advised that Acer notified the FDA in the resubmission that the third-party contract packaging manufacturer is ready for inspection. FDA did not cite any other approvability issues in the CRL pertaining to the NDA, nor request any additional clinical or pharmacokinetic studies be conducted prior to FDA action. According to Acer, additional existing nonclinical information as requested by the FDA in the CRL but identified as "not an approvability issue," as well as labeling and other routine updates to the original NDA, were provided in the resubmission of the NDA.

About ACER-001

ACER-001 (sodium phenylbutyrate) is being developed for the treatment of various inborn errors of metabolism, including UCDs and Maple Syrup Urine Disease (MSUD). ACER-001 is a nitrogen-binding agent in development for use as adjunctive therapy in the chronic management of patients with UCDs involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). ACER-001 is a polymer coated formulation that, when taken within 5 minutes, helps prevent the coating from dissolving. ACER-001 has been granted orphan drug designation by the FDA for MSUD. ACER-001 is an investigational product candidate which has not been approved by FDA, the European Medicines Agency (EMA), or any other regulatory authority. There can be no assurance that the FDA inspection of the third-party contract packaging manufacturer facility will be satisfactory, that such inspection is the only impediment to FDA approval of a resubmitted NDA, that a resubmitted NDA will otherwise be approved by the FDA, or that ACER-001 will be approved for any indication.

About RELIEF THERAPEUTICS Holding SA

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 has delivered to Relief a diverse pipeline of marketed and development-stage programs.



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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 RLTY. For more information, visit www.relieftherapeutics.com
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Disclaimer: This communication expressly or implicitly contains certain forward-looking statements concerning RELIEF THERAPEUTICS Holding SA and its businesses. Such statements involve certain known and unknown risks, uncertainties and other factors, including (i) whether the resubmitted NDA for ACER-001 will be accepted for review by the FDA, (ii) if the resubmitted NDA filing is accepted for review, the timing of FDA review of the resubmitted NDA, (iii) if the resubmitted NDA is accepted for review, whether the FDA will approve Acer's NDA for ACER-001, (iv) whether RELIEF THERAPEUTICS Holding SA will submit an application for approval of ACER-001 in Europe and the timing of filing such application, (v) whether any such application submitted to European authorities seeking marketing authorization for ACER-001 for the treatment of patients in Europe with UCDS will be approved, and (vi) those other risks, uncertainties and factors described in RELIEF THERAPEUTICS Holding SA's press releases and filings with the SIX Swiss Exchange and the U.S. Securities and Exchange Commission, all of 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.

