



Ad hoc announcement pursuant to Art. 53 LR

Acer Therapeutics and Relief Therapeutics Announce FDA Acceptance for Review of NDA Resubmission for ACER-001 for Treatment of UCDS

Prescription Drug User Fee Act (PDUFA) target action date set for January 15, 2023

NEWTON, MA and GENEVA, SWITZERLAND – July 28, 2022 – Acer Therapeutics Inc. (Nasdaq: ACER) (Acer) and its collaboration partner, RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLTF, RLTY) (Relief), today announced the U.S. Food and Drug Administration (FDA) has accepted for review Acer's resubmitted New Drug Application (NDA) for ACER-001 (sodium phenylbutyrate) for oral suspension for the treatment of patients with urea cycle disorders (UCDs). The FDA designated the NDA as a Class 2 resubmission and set a Prescription Drug User Fee Act (PDUFA) target action date of January 15, 2023.

"We are very pleased to receive confirmation that the FDA is commencing its review of our NDA resubmission," said Chris Schelling, Founder & Chief Executive Officer of Acer. "We have notified the FDA that our third-party contract packaging manufacturer is ready for inspection and are hopeful that the Agency's review can be completed in a timely manner. While NDA approval is not assured, if approval is received, we are prepared to execute on our comprehensive launch plan and provide a new treatment option to underserved UCDs patients. These efforts reinforce our ongoing commitment to developing new and differentiated treatment options for those affected by rare diseases."

In June 2022, as previously announced, the FDA issued Acer a Complete Response Letter (CRL) stating that satisfactory inspection of Acer's third-party contract packaging manufacturer is required before the ACER-001 NDA may be approved. Acer notified the FDA in the NDA resubmission that the third-party contract packaging manufacturer is ready for inspection. The 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. 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 required updates to the original NDA, were provided in the resubmission of the NDA.

There can be no assurance that ACER-001 will be approved for any indication.

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.

About Acer Therapeutics Inc.

Acer is a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs. Acer's pipeline includes four investigational programs: ACER-001 (sodium phenylbutyrate) for treatment of various inborn errors of metabolism, including urea cycle disorders (UCDs) and Maple Syrup Urine Disease (MSUD); ACER-801 (osanetant) for treatment of induced Vasomotor Symptoms (iVMS); EDSIVO™ (celiprolol) for treatment of vascular Ehlers-Danlos syndrome (vEDS) in patients with a confirmed type III collagen (COL3A1) mutation; and ACER-2820 (emetine), a host-directed therapy against a variety of viruses, including cytomegalovirus, Zika, dengue, Ebola and COVID-19. For more information, visit www.acertx.com.

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 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](#).

Acer Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release are forward-looking statements. Examples of such statements include, but are not limited to, statements about our plans if NDA approval is received, including our launch plan and intent to provide a new treatment option to underserved UCDs patients, as well as statements regarding our ongoing commitment to developing new and differentiated treatment options for those affected by rare diseases. Our pipeline products are under investigation and their safety and efficacy have not been established and there is no guarantee that any of our investigational products in development will receive health authority approval or become commercially available for the uses being investigated. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, risks related to the drug development and the regulatory approval process, including the timing and requirements of regulatory actions. We disclaim any intent or obligation to update these forward-looking statements to reflect events or circumstances that exist after the date on which they were made. You should review additional disclosures we make in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. You may access these documents for no charge at <http://www.sec.gov>.

Relief Forward-Looking Statements

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 FDA will approve Acer's NDA for ACER-001, (ii) whether RELIEF THERAPEUTICS Holding SA will submit an application for approval of ACER-001 in Europe and the timing of filing such application, (iii) 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 (iv) 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.

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