Ad hoc announcement pursuant to Art. 53 LR

Relief Therapeutics and Acer Therapeutics Announce that the European Commission Has Granted Orphan Drug Designation for ACER-001 in Maple Syrup Urine Disease

Orphan designation provides potential for up to 10-year market exclusivity in the EU upon regulatory approval

GENEVA, SWITZERLAND and NEWTON, MA – August 12, 2022 – RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLFTF, RLFTY) (Relief), and its collaboration partner, Acer Therapeutics Inc. (Nasdaq: ACER) (Acer), today announced that the European Commission has granted orphan medicinal product designation in the EU to ACER-001 (sodium phenylbutyrate) for the potential treatment of patients with Maple Syrup Urine Disease (MSUD). ACER-001 was granted orphan drug designation by the U.S. Food and Drug Administration (FDA) in the U.S. for MSUD in 2014.

"Orphan designation by the European Commission is another important milestone for the ACER-001 program that provides further validation of the important role we believe ACER-001 will play in the potential treatment of multiple rare diseases," stated Raghuram (Ram) Selvaraju, Ph.D., Chairman of the Board of Directors of Relief. "We look forward to the continued advancement of ACER-001 in MSUD and Urea Cycle Disorders."

"We are very pleased to receive orphan medicinal product designation in both the U.S. and now the EU, underscoring the urgent need for an approved treatment for MSUD," said Adrian Quartel, MD, FFPM, Chief Medical Officer of Acer. "Currently, the only treatment option for patients with MSUD is a lifelong, protein-restricted diet, however, they still remain at serious risk for a wide range of life-threatening complications."

Orphan drug designation is granted to medicines that treat or prevent a life-threatening or chronically debilitating rare disease, with a prevalence in the EU of not more than 5 in 10,000, and with either no currently approved method of prevention or treatment, or with significant benefit to those affected by the disease. The designation potentially provides certain benefits to ACER-001, including the potential for up to 10-year EU market exclusivity upon regulatory approval, if received, reductions in EMA application fees, and access to study protocol assistance.

Rationale for ACER-001 Treatment in MSUD

Multiple investigational trials evaluating sodium phenylbutyrate in urea cycle disorder (UCD) patients suggest treatment with sodium phenylbutyrate is associated with selective reduction in branched chain amino acids (BCAA) despite adequate restricted dietary protein intake.[1,2,3,4] Analysis of data from a longitudinal multicenter study of 553 UCD patients treated with sodium phenylbutyrate demonstrated that sodium phenylbutyrate decreased plasma BCAA in patients with UCDs and could serve as a therapy in maple syrup urine disease and other common complex disorders with dysregulation of BCAA metabolism.[2]

Based on this clinical observation, investigators at Baylor College of Medicine explored the potential of sodium phenylbutyrate treatment to lower BCAA and corresponding branched-chain α-ketoacid (BCKA) levels in both healthy subjects and patients with MSUD. The investigators found that sodium phenylbutyrate, when dosed over three days, showed a statistically significant reduction of leucine in all three healthy subjects and in three out of the five MSUD patients who participated in the trial.[5]

In November 2020, study results evaluating the effect of sodium phenylbutyrate in the management of acute metabolic decompensation in pediatric MSUD patients (n=10) were published by investigators from Istanbul University-Cerrahpasa Medical Faculty in the peer-reviewed *Journal of Pediatric Endocrinology and Metabolism* showing a significant reduction in leucine levels in MSUD patients experiencing an acute attack.[6] The results suggested that sodium phenylbutyrate could be safely administered in combination with emergency protocol using other active pharmaceuticals and supports additional investigation of potential clinical benefit beyond emergency protocol alone.

About MSUD

MSUD is a rare inherited disorder caused by a deficiency of branched-chain alpha-keto acid dehydrogenase complex, resulting in elevated blood levels of the (BCAA) leucine, valine, and isoleucine, as well as the associated (BCKA) in a patient's blood. Left untreated, this can result in neurological damage, mental disability, coma, or death. The most severe presentation of MSUD, known as "classic" MSUD, accounts for 80% of cases and can result in neonatal onset with encephalopathy and coma. Although metabolic management of the disease is possible via a highly restrictive diet, the outcome is unpredictable, and a significant portion of affected individuals are mentally impaired or experience neurological complications.

MSUD is typically diagnosed at birth via newborn screening and incidence is estimated at 1 in 185,000 people worldwide and 1 in 220,000 people in the United States.[7] The disorder occurs more frequently in the Old Order Mennonite population, with an estimated incidence of about 1 in 380 newborns, and the Ashkenazi Jewish population, with an estimated incidence of 1 in 26,000.[8]

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 (sodium phenylbutyrate) is an immediate-release, polymer coated, multi-particulate formulation of sodium phenylbutyrate for oral administration via suspension, that is designed to improve palatability. ACER-001 (sodium phenylbutyrate) has been granted orphan drug designation by the FDA for MSUD. In July 2022, the FDA accepted Acer's NDA resubmission (Class 2) and assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 15, 2023. This investigational product candidate has not been approved by FDA, the European Medicines Agency (EMA), or any other regulatory authority. There can be no assurance that the resubmitted ACER-001 NDA for UCDs will be approved by the FDA, or that ACER-001 (sodium phenylbutyrate) will otherwise be approved for any indication.

About RELIEF THERAPEUTICS Holding SA

Relief is a Swiss, commercial-stage, biopharmaceutical company focused on identification, development and commercialization of novel, patent protected products intended for the treatment of metabolic, dermatological and pulmonary rare diseases with a portfolio of clinical and marketed assets that serve unmet patient needs. 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 develop aviptadil for several rare pulmonary

indications; 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.

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.

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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 for the treatment of UCDs, (ii) whether RELIEF THERAPEUTICS Holding SA will submit an application for approval of ACER-001 in Europe for the treatment of UCDs and the timing of filing such application, (iii) whether any application submitted to European authorities seeking marketing authorization for ACER-001 for the treatment of patients in Europe with UCDs will be approved, (iv) whether the FDA will approve Acer's IND to evaluate ACER-001 for the treatment of MSUDs, (v) the timing of Acer's Phase 2b trial evaluating ACER-001 for the treatment of MSUDs, (vi) whether ACER-

001's currently proposed trial and any future required trials of ACER-001 for MSUDs will be undertaken and successful, (vii) whether ACER-001 will ever be approved for the treatment of MSUDs in the United States, (viii) whether Relief will ever file the necessary applications in Europe to seek the right to commercialize ACER-001 in Europe for the treatment of MSUDs and whether any such applications filed will be granted, and (ix) 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.

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 the role we believe ACER-001 could play in the potential treatment of multiple rare diseases and its continued advancement in MSUD and Urea Cycle Disorders, potential results of the investigational trial and the potential of ACER-001 to reduce certain amino acids and leucine levels in MSUD patients, the rationale for ACER-001 treatment in MUSD, the potential outcomes of having MUSD, and statements about our resubmission of an ACER-001 NDA for UCDs and potential regulatory approval thereof. 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.

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