Ad hoc announcement pursuant to Art. 53 LR of the SIX Swiss Exchange

Acer Therapeutics and Relief Therapeutics Announce Presentation of ACER-001 Data at the Society for Inherited Metabolic Disorders Annual Meeting

NEWTON, MA and GENEVA, SWITZERLAND – April 12, 2022 – Acer Therapeutics Inc. (Nasdaq: ACER) ("Acer") and its collaboration partner, Relief Therapeutics Holding SA (SIX: RLF, OTCQB: RLFTF, RLFTY) ("Relief"), today announced the presentation of data evaluating the bioavailability, bioequivalence and taste attributes of taste-masked sodium phenylbutyrate (ACER-001) compared to sodium phenylbutyrate (BUPHENYL®) powder during poster sessions at the recent Society for Inherited Metabolic Disorders (SIMD) Annual Meeting on April 10-13, 2022 in Orlando, Florida.

"These data further support our belief that, if approved, ACER-001 could offer an alternative to current therapies that may lead to meaningful clinical outcomes in UCDs patients," said Adrian Quartel, MD, CMO of Acer. "We are pleased with the outcomes of these studies and look forward to presenting them at future conferences."

"We are highly encouraged by the results of these bioavailability, bioequivalence and taste attribute studies of ACER-001," added Raghuram (Ram) Selvaraju, Chairman of Relief. "We look forward to the U.S. Food and Drug Administration's decision on the Prescription Drug User Fee Act (PDUFA) target action date on June 5, 2022."

ACER-001 Data Presented at SIMD

A copy of each poster presentation from the SIMD Meeting is available on Acer's website at: https://www.acertx.com/publications-and-presentations/.

<u>The Pharmacokinetics of Taste-Masked Sodium Phenylbutyrate (ACER-001) for the Treatment of Urea Cycle Disorders Under Fasting and Fed Conditions in Healthy Volunteers</u>[1]

This poster summarizes results from two Phase 1 bridging studies that evaluated the bioavailability and bioequivalence of taste-masked sodium phenylbutyrate (ACER-001) compared to sodium phenylbutyrate (BUPHENYL®) powder. The objectives of the two studies were to determine the bioequivalence of taste-masked sodium phenylbutyrate (ACER-001) administered as a suspension relative to sodium phenylbutyrate (BUPHENYL®) powder administered as a solution in healthy adult volunteers after a single dose under fasting and fed conditions, and to assess the effect of a high-fat meal on the pharmacokinetics (PK) of taste-masked sodium phenylbutyrate (ACER-001).

The data presented concluded that taste-masked sodium phenylbutyrate (ACER-001) was bioequivalent to sodium phenylbutyrate (BUPHENYL®) powder under both fed and fasting conditions. Higher levels of phenylbutyrate (PBA) and phenylacetate (PAA), a conjugate base of phenylacetic acid, were observed when taste-masked sodium phenylbutyrate (ACER-001) was administered under fasting versus fed conditions. A similar reduction in the PK of sodium phenylbutyrate (BUPHENYL®) powder under fed conditions was observed between the fasted and fed studies. Adverse events in these studies showed no major safety signals and were similar to sodium phenylbutyrate (BUPHENYL®).

These studies suggest investigating administration of nitrogen scavengers under fasting conditions, which may ultimately provide lower dose options and increase dosing flexibility.

Taste-Masked Coating of Sodium Phenylbutyrate (ACER-001) Improves the Palatability of Sodium Phenylbutyrate for Treatment of Urea Cycle Disorders[2]

The second poster presented at SIMD details results from two Phase 1, open-label, repeated measures, taste assessment studies of taste-masked sodium phenylbutyrate (ACER-001) and sodium phenylbutyrate (BUPHENYL®) powder. The studies included healthy panelists who were required to complete a training program for a minimum of 6 months that educated panelists on the identification, description, and quantification of sensory attributes of products.

The objective of the two taste assessment studies was to identify and quantify the intensity of perceived flavor attributes of taste-masked sodium phenylbutyrate (ACER-001) relative to sodium phenylbutyrate (BUPHENYL®) powder. Results from both studies concluded that taste-masked sodium phenylbutyrate (ACER-001) was shown to have overall lower flavor intensity scores than sodium phenylbutyrate (BUPHENYL®) powder when administered within five minutes of preparation.

About UCDs

The urea cycle is a series of biochemical reactions that occur primarily in the liver, which converts toxic ammonia produced by the breakdown of protein and other nitrogen-containing molecules in the human body into urea for excretion. UCDs are a group of disorders caused by genetic mutations that result in a deficiency in any one of the six enzymes or two of the amino acid transporters, which can lead to an excess accumulation of ammonia in the bloodstream, a condition known as hyperammonemia. Acute hyperammonemia can cause lethargy, somnolence, coma, and multi-organ failure, while chronic hyperammonemia can lead to headaches, confusion, lethargy, failure to thrive, behavioral changes, and learning and cognitive deficits. Common symptoms of both acute and chronic hyperammonemia also include seizures and psychiatric symptoms.

Medications for UCDs are primarily comprised of nitrogen scavenger drugs, which are substances that provide alternative excretion pathways for nitrogen by bypassing the urea cycle. The use of these alternative pathways for nitrogen removal is important for the management of acute episodes of hyperammonemia and are also included as part of a long-term treatment regimen for UCDs patients. According to a 2016 study by Shchelochkov et al., published in *Molecular Genetics and Metabolism Reports*[3], while nitrogen scavenging medications are effective in helping to manage UCDs, non-compliance with treatment is common. Reasons given for non-compliance include the unpleasant taste associated with some available medications, the frequency with which medication must be taken and the high cost of the medication.

About ACER-001

ACER-001 (sodium phenylbutyrate) is being developed for the treatment of various inborn errors of metabolism, including UCDs and 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's multi-particulate dosage formulation for oral administration is designed to minimize the aversive taste and odor[4] of sodium phenylbutyrate while quickly dissolving in the stomach. The ACER-001 NDA for UCDs is currently under FDA review with a PDUFA target action date of June 5, 2022. ACER-001 is also being developed for MSUD and has been granted orphan drug designation by the FDA for this indication. 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 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 infectious diseases, including COVID-19. Each of Acer's product candidates is believed to present a comparatively de-risked profile, having one or more of a favorable safety profile, clinical proof-of-concept data, mechanistic differentiation and/or accelerated paths for development through specific programs and procedures established by the FDA. In March 2021, Acer entered into a Collaboration and License Agreement with Relief for development and commercialization of ACER-001. 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's 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 through Relief's collaboration partner in the U.S., NeuroRx, Inc. Relief also 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 urea cycle disorders and Maple Syrup Urine Disease. Acer's new drug application for ACER-001 for use as a treatment of urea cycle disorders was recently accepted by the FDA for filing with a PDUFA decision date of June 5, 2022. Finally, Relief's acquisitions last summer 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**.

References

1. Steiner R, et al. The Pharmacokinetics of Taste-Masked Sodium Phenylbutyrate (ACER-001) for the Treatment of Urea Cycle Disorders Under Fasting and Fed Conditions in Healthy Volunteers. SIMD April 2022.
2. Cedarbaum S, et al. Taste-Masked Coating of Sodium Phenylbutyrate (ACER-001) Improves the Palatability of Sodium Phenylbutyrate for Treatment of Urea Cycle Disorders. SIMD April 2022.
3. Shchelochkov et al. Molecular Genetics & Metabolism Reports 8 (2016) 43-47.
4. Peña-Quintana L, et al. Profile of sodium phenylbutyrate granules for the treatment of urea-cycle disorders: patient perspectives. Patient Prefer Adherence. 2017 Sep 6;11:1489-1496.

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 regarding strategy, future operations, timelines for clinical study enrollment or regulatory actions, or otherwise, future financial position, future revenues, projected expenses, regulatory submissions, actions or approvals, cash position, liquidity, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to the potential for our product candidates to safely and effectively treat diseases and to be approved for marketing; the commercial or market opportunity of any of our product candidates in any target indication and any territory; our ability to secure the additional capital necessary to fund our various product candidate development programs; the adequacy of our capital to support our future operations and our ability to successfully fund, initiate and complete clinical trials and regulatory submissions for ACER-001, ACER-801, EDSIVO™ or our other products; the ability to protect our intellectual property rights; our strategy and business focus; and the development, expected timeline and commercial potential of any of our product candidates. 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 and uncertainties associated with the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources to fund our various product candidate development programs and to meet our business objectives and operational requirements, the fact that the results of earlier studies and trials may not be predictive of future clinical trial results, the protection and market exclusivity provided by our intellectual property, risks related to the drug development and the regulatory approval process, including the timing and requirements of regulatory actions, and the impact of competitive products and technological changes. 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. 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 be able to submit an application for approval of ACER-001 in Europe in Q2/Q3 2022 (or at all), (iii) whether any such application submitted to European authorities seeking marketing authorization for ACER-001 for the treatment of patient 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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