**Ad hoc announcement pursuant to Art. 53 LR**

**Acer Therapeutics and Relief Therapeutics Announce FDA Acceptance for Filing of New Drug Application for ACER-001 to Treat Urea Cycle Disorders**

*FDA sets PDUFA target action date of June 5, 2022*

**NEWTON, MA and GENEVA, SWITZERLAND – October 6, 2021 –** Acer Therapeutics Inc. (Nasdaq: ACER) ("Acer") and its collaboration partner, RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLFTF) ("Relief"), today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for ACER-001 (sodium phenylbutyrate) for the treatment of patients with Urea Cycle Disorders (UCDs). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 5, 2022.

Acer's 505(b)(2) NDA is supported by results from two previously announced bioequivalence (BE) trials in which ACER-001 showed similar relative bioavailability for both phenylbutyrate (PBA) and phenylacetate (PAA), the active metabolite of sodium phenylbutyrate, compared to the reference listed drug, BUPHENYL® (sodium phenylbutyrate).

"With FDA commencing a substantive review of our NDA, ACER-001 is one step closer to potentially providing an alternative treatment option for patients with UCDs," said Chris Schelling, Chief Executive Officer and Founder of Acer. "We look forward to working with the FDA during their review of our application. In addition, we continue to collaborate with our partners to ensure we are well positioned to support a successful commercial launch of ACER-001, subject to FDA approval."

Jack Weinstein, Chief Financial Officer and Treasurer of Relief, added, "Our collaboration with Acer is thriving and we are pleased with the progress they have made in advancing ACER-001. In parallel with Acer's activities, we continue to execute on our global commercial strategy for ACER-001 which includes our intended submission of a Marketing Authorization Application (MAA) for the treatment of patients with UCDs in Europe in Q2/Q3 2022."

Parties interested in the ACER-001 program for UCDs may sign up for updates at:
https://www.acertx.com/rare-disease-research/acer-001-for-urea-cycle-disorders-ucds/

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 is no guarantee that this product candidate will receive regulatory authority approval in any territory or become commercially available for the indications under investigation.

**About UCDs**

UCDs are a group of disorders caused by genetic mutations that result in a deficiency in one of the six enzymes that catalyze the urea cycle, 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.[1,2] The current treatment of patients with UCDs consists of dietary management to limit ammonia production in conjunction with medications that provide alternative pathways for the removal of ammonia from the bloodstream. Some patients may also require individual branched-chain amino acid supplementation.

Current medical treatments for patients with UCDs include nitrogen scavengers, RAVICTI® and BUPHENYL®, in which the active pharmaceutical ingredients are glycerol phenylbutyrate and sodium phenylbutyrate, respectively. According to a 2016 study by Shchelochkov et al., published in *Molecular Genetics and Metabolism Reports*, while nitrogen scavenging medications have been shown to be effective in helping to manage ammonia levels in some patients with UCDs, non-compliance with treatment is common. Reasons referenced for non-compliance associated with some available medications include unpleasant taste, frequency with which medication must be taken, required number of pills, and the high cost of the medication.[3]

**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). The formulation is a multi-particulate dosage formulation for oral administration consisting of a core center, a layer of active drug, and a taste-masked coating designed to avoid the bitter taste of sodium phenylbutyrate in the mouth while quickly dissolving in the low pH of the stomach. Acer 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 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 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 to Relief a diverse pipeline of marketed and development-stage programs, a commercial infrastructure in selected European countries and an internal, R&D capability, which Relief hopes to leverage for both internal pipeline products as well as for third party product development on a fee for service basis.

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 Relief on LinkedIn.

**References**

1. Ah Mew N, et al. Urea cycle disorders overview. Gene Reviews. Seattle, Washington: University of Washington, Seattle; 1993.
2. Häberle J, et al. Suggested guidelines for the diagnosis and management of urea cycle disorders. Orphanet Journal of Rare Diseases. 2012;7(32).
3. Shchelochkov OA, et al. Barriers to drug adherence in the treatment of urea cycle disorders: Assessment of patient, caregiver and provider perspectives. *Mol Genet Metab.* 2016;8:43-47.


**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, 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; 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 Quarterly Reports on Form 10-Q and 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 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, (iv) whether RLF-100 (aviptadil) will receive emergency use authorization in the United States, (v) whether RLF-100 (aviptadil) will ever be submitted for authorization in Europe, (vi) whether Relief's ongoing disputes with its U.S. collaboration partner for RLF-100 (aviptadil) can be resolved amicably, and (vii) those other risks, uncertainties and factors described in Relief's annual and periodic filings with the SIX Stock Exchange, 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.


| **CORPORATE CONTACTS** | |
|---|---|
| Acer Therapeutics:<br>Jim DeNike<br>Acer Therapeutics Inc.<br>jdenike@acertx.com<br>+1 844-902-6100 | RELIEF THERAPEUTICS Holding SA:<br>Jack Weinstein<br>Chief Financial Officer and Treasurer<br>contact@relieftherapeutics.com |

| **INVESTOR RELATIONS CONTACTS** | |
|---|---|
| Acer Therapeutics:<br>Hans Vitzthum | RELIEF THERAPEUTICS Holding SA:<br>Michael Miller |

## Ad hoc announcement pursuant to Art. 53 LR

| | |
|---|---|
| LifeSci Advisors<br>hans@lifesciadvisors.com<br>+1 617-430-7578 | Rx Communications Group<br>mmiller@rxir.com<br>+1-917-633-6086 |

# # #