



Relief and Acer Therapeutics Sign Collaboration and License Agreement for Worldwide Development and Commercialization of ACER-001 for the Treatment of Urea Cycle Disorders and Maple Syrup Urine Disease

 $Relief to \ potentially \ pay \ Acer \ up \ to \ \$36 \ million \ and \ royalties \ in \ exchange \ for \ net \ profit \ share \ and \ territory \ rights$

ACER-001 pre-NDA meeting with U.S. FDA scheduled in Q2 2021

Geneva, Switzerland, and Newton, MA, USA, March 22, 2021 – RELIEF THERAPEUTICS Holding AG (SIX: RLF,OTCQB: RLFTF) ("Relief"), a biopharmaceutical company with its lead compound RLF-100™ (aviptadil) in advanced clinical development to treat severe COVID-19 patients, and Acer Therapeutics Inc. (Nasdaq: ACER) ("Acer"), a pharmaceutical company focused on the acquisition, development, and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs, today announced that the companies entered into a Collaboration and License Agreement ("CLA") for worldwide development and commercialization of ACER-001. ACER-001 is a proprietary powder formulation of sodium phenylbutyrate (NaPB) designed to be both taste-masked and immediate release.

Under the terms of the CLA, Acer will receive an approximately \$10 million cash payment within 15 business days of CLA execution (originally \$14 million, to be offset by repayment of the \$4.0 million outstanding balance of the prior loan, plus interest, from Relief to Acer). Relief will also pay Acer up to \$20 million in U.S. development and commercial launch costs for the UCDs and MSUD indications. Acer will retain development and commercialization rights in the U.S., Canada, Brazil, Turkey and Japan. The companies will split net profits from Acer's territories 60%:40% in favor of Relief. In addition, Relief has licensed the rights for the rest of the world, where Acer will receive from Relief a 15% royalty on all revenues received in Relief's territories. Acer may also receive a total of \$6 million in development milestone payments following the first European (EU) marketing approvals for UCDs and MSUD.

Jack Weinstein, Chief Financial Officer and Treasurer of Relief, said, "We are excited to continue moving forward with the Acer team to develop and commercialize ACER-001 around the globe to address important unmet needs for patients suffering from these rare diseases. This collaboration is an important step in Relief's plan to build a diversified late-stage pipeline beyond our lead candidate, RLF-100™, which is currently in development for the treatment of respiratory illnesses due to COVID-19 infection. We are pleased to have been able to conclude this agreement, as the advanced stage of development and market opportunity with ACER-001 make this compound a perfect fit for Relief's strategy."

Chris Schelling, Acer's CEO and Founder, said, "Our collaboration with Relief will provide important resources and additional expertise to advance the development of ACER-001 toward our goal of bringing this product candidate to patients suffering from UCDs and MSUD. We look forward to partnering with the team at Relief to advance this program and to potentially provide a much-needed treatment option for patients with these rare and debilitating diseases."

An ACER-001 pre-NDA meeting with the U.S. FDA is scheduled to occur in the second quarter of 2021. Acer expects to receive official meeting minutes approximately 30 days after the meeting.





ACER-001 is an investigational product being studied for the treatment of patients with UCDs and MSUD and has not been approved by the U.S. FDA or any regulatory agency outside the U.S. for any indication. There can be no assurance that if submitted, a New Drug Application or equivalent will be accepted by the U.S. FDA or any other regulatory agency for filing and review or, if filed, that it will be approved.

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ABOUT UREA CYCLE DISORDERS (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 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 UCDs include nitrogen scavengers, RAVICTI® and BUPHENYL®, in which the active pharmaceutical ingredients are glycerol phenylbutyrate (GPB) and sodium phenylbutyrate (NaPB), 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, the frequency with which medication must be taken, the number of pills, and the high cost of the medication.³

ABOUT MAPLE SYRUP URINE DISEASE

MSUD is a rare inherited disorder caused by defects in the mitochondrial branched-chain ketoacid dehydrogenase complex, which results in elevated blood levels of the branched-chain amino acids (BCAA), leucine, valine, and isoleucine, as well as the associated branched-chain ketoacids (BCKA) in a patient's blood. Left untreated, this can result in neurological damage, mental disability, coma or death. There are currently no approved pharmacologic therapies in the U.S. or the European Union for MSUD. Treatment of MSUD consists primarily of a severely restricted diet to limit the intake of BCAA, with aggressive medical interventions when blood-levels of BCAA or BCKA become elevated.

ABOUT ACER-001

ACER-001 is a proprietary powder formulation of sodium phenylbutyrate (NaPB). The formulation is designed to be both taste-masked and immediate release. ACER-001 is being developed using a microencapsulation process for the treatment of various inborn errors of metabolism, including UCDs and MSUD. ACER-001 microparticles consist of a core center, a layer of active drug, and a taste-masking coating that quickly dissolves in the stomach, to avoid a bitter taste while still allowing for rapid systemic release. If ACER-001 is approved, its taste-masked properties could make it a compelling alternative to existing NaPB-based treatments, as the unpleasant taste associated with NaPB is cited as a major impediment to patient compliance with those





treatments.³ Acer has been granted orphan drug designation by the FDA for the MSUD indication. ACER-001 is under clinical investigation and its safety and efficacy have not been established. There is no guarantee that this product candidate will receive U.S. FDA approval or become commercially available for the uses being investigated.

ABOUT RELIEF THERAPEUTICS HOLDING AG

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 the worldwide 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.

RELIEF THERAPEUTICS Holding AG 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 us 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 programs: ACER-001 (sodium phenylbutyrate) for the treatment of various inborn errors of metabolism, including urea cycle disorders (UCDs) and Maple Syrup Urine Disease (MSUD); EDSIVO™ (celiprolol) for the treatment of vascular Ehlers-Danlos syndrome (vEDS) in patients with a confirmed type III collagen (COL3A1) mutation; ACER-801 (osanetant) for the treatment of induced Vasomotor Symptoms (iVMS); 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 U.S. FDA. On March 19, 2021, Acer entered into a Collaboration and License Agreement with Relief Therapeutics for worldwide development and commercialization of ACER-001.

For more information, visit www.acertx.com.

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.





RELIEF FORWARD-LOOKING STATEMENTS

This communication expressly or implicitly contains certain forward-looking statements concerning RELIEF THERAPEUTICS Holding AG and its businesses. The results reported herein may or may not be indicative of the results of future and larger clinical trials for ACER-001 for the treatment of UCDs and MSUD, nor whether the ongoing clinical trials of Relief's lead compound, RLF-100™ (aviptadil) in advanced clinical development to treat respiratory deficiency due to COVID-19, will be successful. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of RELIEF THERAPEUTICS Holding AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. RELIEF THERAPEUTICS Holding AG 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 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 benefits and results of the Collaboration and License Agreement between Acer and Relief with respect to ACER-001; the potential for ACER-001 to target diseases; the adequacy of Acer's capital to support its future operations and its ability to successfully continue its development programs; Acer's ability to secure the additional capital necessary to fund its various product candidate development programs; and the development and commercial potential of any of Acer's product candidates including ACER-001. Acer 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 Acer's ability to benefit from and achieve the results contemplated by the Collaboration and License Agreement with Relief, the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources to fund Acer's various product candidate development programs and to meet its 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 Acer's intellectual property, risks related to the drug discovery and the regulatory approval process and the impact of competitive products and technological changes. Acer disclaims 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 Acer makes in its filings with the Securities and Exchange Commission, including its Quarterly Reports on Form 10-Q and its Annual Report on Form 10-K. You may access these documents for no charge at http://www.sec.gov.





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