



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

Acer to receive \$1 million payment to obtain exclusivity and a \$4 million loan from Relief

Companies working toward negotiation and execution of a definitive collaboration and license agreement by June 30, 2021

Geneva, Switzerland, and Newton, MA, USA, January 25, 2021 – RELIEF THERAPEUTICS Holding AG (SIX: RLF,OTCQB: RLFTF) ("Relief"), a biopharmaceutical company with its lead compound RLF-100TM (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 have signed an Option Agreement providing exclusivity for the right to negotiate a potential collaboration and license agreement for worldwide development and commercialization for ACER-001. ACER-001 (sodium phenylbutyrate) powder is a taste-masked, immediate release proprietary formulation in development for the treatment of urea cycle disorders (UCDs) and Maple Syrup Urine Disease (MSUD).

Under the terms of the Option Agreement, Acer will receive from Relief a \$1 million non-refundable payment in return for exclusivity until June 30, 2021 to negotiate and enter into a definitive collaboration and license agreement between Acer and Relief for the development of ACER-001. Further, in connection with entering into the Option Agreement, Relief will make a \$4.0 million loan to Acer. The loan, which will be secured by a lien on all of Acer's assets, will bear interest at the rate of 6% per annum and will be due in one year.

Under the terms of the proposed collaboration and license agreement, the key terms of which are set forth in the Option Agreement, if a definitive agreement is executed pursuant to these terms and closed by June 30, 2021, Acer will receive \$15 million in cash (net \$10 million, inclusive of the \$1 million payment and offset by a repayment of the \$4 million loan from Relief). In addition, Relief will agree to pay up to \$20 million in U.S. development and commercial launch costs for the UCDs and MSUD indications. Further, 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. Relief will also license the rights for the rest of the world, where Acer will receive from Relief a 15% net sales royalty on all revenues received in Relief's territories. Acer could also receive a total of \$6 million in milestones based on the first European (EU) marketing approvals for UCDs and MSUD. There can be no assurance, however, that a definitive agreement will be successfully negotiated and executed between the parties on these terms, on other mutually acceptable terms, or at all. Except for the \$1.0 million upfront payment to Acer and the \$4.0 million one-year secured loan from Relief to Acer, the remaining proposed terms of the collaboration are not binding and are subject to change as a result of further diligence by Relief and negotiation of a definitive collaboration and license agreement between the parties.





Jack Weinstein, Relief's CFO and Treasurer, said, "We are excited about the opportunity to work with the Acer team to potentially develop and commercialize ACER-001 worldwide. This partnership is Relief's first initiative to build a pipeline of drugs beyond RLF-100™. While our core focus remains squarely on the rapid advancement of RLF-100™ for treatment of respiratory conditions, primarily acute respiratory distress syndrome (ARDS) due to COVID-19 infection, we are committed to establishing a diversified marketed product portfolio. ACER-001's stage of maturity fits perfectly within our strategic plan."

Chris Schelling, Acer's CEO and Founder, said, "I believe Relief shares the same values and vision that Acer has in supporting the rare disease community. This potential collaboration could provide important resources and additional expertise to help bring ACER-001 to patients worldwide suffering from debilitating diseases like UCDs and MSUD. We very much look forward to the possibility of working with the Relief team."

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ABOUT UREA CYCLE DISORDERS (UCDS)

Urea Cycle Disorders (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 can 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.²

ABOUT MAPLE SYRUP URINE DISEASE

Maple Syrup Urine Disease (MUSD) is a rare but serious inherited condition whereby the human body cannot process certain amino acids, causing a harmful build-up of substances in the blood and urine. The human body breaks down protein foods such as meat and fish into amino acids. Other than a highly restricted diet of branched-chain amino acid (BCCA) free synthetic foods and formula, there are no currently approved treatments for MSUD.

ABOUT ACER-001

ACER-001 is a 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, allowing taste to be neutralized 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 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 of natural origin (peptides and proteins) with a history of clinical testing and use in human patients or a strong scientific rationale. Currently, Relief is concentrating its efforts on developing new treatments for respiratory disease indications. Its lead drug candidate RLF- 100^{TM} (aviptadil) is being investigated in two placebo-controlled U.S. phase 2b/3 clinical trials in respiratory deficiency due to COVID-19. Relief holds a patent issued in the United States and various other countries covering potential formulations of RLF- 100^{TM} .

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 FDA. 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, Inc. 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 severe COVID-19 patients, 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 do 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 structure, terms, timing and entry into a definitive agreement for the proposed collaboration between Acer and Relief with respect to ACER-001; the shared values, vision and results of the potential collaboration of Acer and Relief; 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 successfully negotiate and execute a definitive collaboration agreement with Relief on the proposed terms, on other mutually acceptable terms, or at all, Acer's ability to repay the \$4 million secured loan from 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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