



Ad hoc announcement pursuant to Art. 53 LR

Acer Therapeutics and Relief Therapeutics Announce Receipt of Notice of Allowance of US Patent Application Covering a Kit Comprising Phenylbutyrate and Sodium Benzoate

Notice of allowance covering these claims further strengthens ACER-001 proprietary position in US; patent expected to be issued in Q4 2022 and expire in 2038

NEWTON, MA and GENEVA, SWITZERLAND – October 3, 2022 – Acer Therapeutics Inc. (Nasdaq: ACER) (Acer) and RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLTF, RLFTY) (Relief) today announced that the US Patent and Trademark Office (USPTO) has issued a Notice of Allowance to Acer for US patent application No. 16/624,834 for claims related to a kit comprising a combination therapeutic product composed of sodium phenylbutyrate or glycerol phenylbutyrate and sodium benzoate. The patent application is exclusively licensed to Acer from Baylor College of Medicine.

“This Notice of Allowance expands ACER-001’s patent protection and adds an additional component to our product expansion strategy as we evaluate how to maximize its potential,” said Jeff Davis, Chief Business Officer at Acer. “The combination of phenylbutyrate and sodium benzoate was synergistic at removing ammonia in healthy subjects based on data from a study published in *Genetics in Medicine* in 2018.¹ As a result, this combination offers the potential to use lower drug doses of each agent while maintaining equivalent ammonia removal in urea cycle disorder patients and becomes part of our lifecycle planning for ACER-001, subject to FDA approval in this indication.”

About Phenylbutyrate and Sodium Benzoate

Phenylbutyrate and sodium benzoate are nitrogen-binding agents that are used in the prevention and treatment of hyperammonemia in patients with UCDs. Sodium benzoate for oral administration is available from compounding pharmacies and is widely used as a food preservative but has not been approved as a single agent by the U.S. Food and Drug Administration (FDA) or any regulatory authority for the treatment of UCDs. Sodium benzoate in combination with sodium phenylacetate is approved in the US and marketed as AMMONUL® (sodium phenylacetate and sodium benzoate) Injection.²

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). ACER-001 is a polymer coated formulation that, when taken within 5 minutes, helps prevent the coating from dissolving. ACER-001 has been granted orphan drug designation by the FDA for MSUD. 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 can be no assurance that ACER-001 will be approved for any indication.

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.

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). The FDA has accepted for review Acer's New Drug Application ("NDA") resubmission under the 505(b)(2) pathway for ACER-001, for oral suspension, for the treatment of patients with UCDs. The FDA designated the NDA as a Class 2 resubmission and set a PDUFA target action date of January 15, 2023. 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](#).

Reference

1. Nagamani et al. A randomized trial to study the comparative efficacy of phenylbutyrate and benzoate on nitrogen excretion and ureagenesis in healthy volunteers. *Genet Med*. 2018 Jul; 20(7): 708–716.
2. https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020645lbl.pdf

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, including statements regarding the expected patent issuance date and duration, our strategy, our positioning, our products and regulatory actions are forward-looking statements. 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 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 and Quarterly Reports on Form 10-Q. 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) the intellectual property protection provided by the patent discussed above, (ii) whether the FDA will approve Acer's NDA for ACER-001 for the treatment of UCDs, (iii) 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, (iv) 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, (v) whether the FDA will approve Acer's IND to evaluate ACER-001 for the treatment of MSUDs, (vi) the timing of Acer's Phase 2b trial evaluating ACER-001 for the treatment of MSUDs, (vii) whether ACER-001's currently proposed trial and any future required trials of ACER-001 for MSUDs will be undertaken and successful, (viii) whether ACER-001 will ever be approved for the treatment of MSUDs in the United States, (ix) 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 (x) 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.

CORPORATE CONTACTS

Acer Therapeutics:

Jim DeNike

Acer Therapeutics Inc.

jdenike@acertx.com

+1-844-902-6100

RELIEF THERAPEUTICS Holding SA:

Jack Weinstein

Chief Financial Officer and Treasurer

contact@relieftherapeutics.com

INVESTOR RELATIONS CONTACTS

Acer Therapeutics:

Nick Colangelo

Gilmartin Group

nick@gilmartinIR.com

+1-339-225-1047

RELIEF THERAPEUTICS Holding SA:

Irina Koffler

LifeSci Advisors

ikoffler@lifesciadvisors.com

+1-917-734-7387

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