



Ad hoc announcement pursuant to Art. 53 LR

Acer Therapeutics and Relief Therapeutics Announce Update on U.S. FDA Review of New Drug Application (NDA) for ACER-001

Citing the need to inspect a third-party contract packaging manufacturer, the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL)

The FDA has not raised any approvability concerns related to the efficacy, safety or pharmacokinetics of ACER-001

NEWTON, MA and GENEVA, SWITZERLAND – June 21, 2022 – Acer Therapeutics Inc. (Nasdaq: ACER) (Acer) and its collaboration partner, RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLTF, RLFTY) (Relief), announced today that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for ACER-001 (sodium phenylbutyrate) for oral suspension for the treatment of patients with urea cycle disorders (UCDs).

The CRL indicates that the FDA cannot approve the NDA in its current form. The CRL states: “[The FDA’s] field investigator could not complete inspection of [Acer’s third-party contract packaging manufacturer], because the facility was not ready for inspection. Satisfactory inspection is required before [the NDA] may be approved. Please notify us in writing when this facility is ready for inspection.”

The FDA did not cite any other approvability issues in the CRL pertaining to the NDA, nor request any additional clinical or pharmacokinetic studies be conducted prior to FDA approval. The FDA did provide one comment in the CRL (identified as “not an approvability issue”) requesting additional existing nonclinical information to be provided in the resubmission of the NDA.

Acer is actively collaborating with its third-party contract packaging manufacturer and cooperating with the FDA to address the FDA’s comments as soon as reasonably possible and currently intends to resubmit the updated NDA for ACER-001 (sodium phenylbutyrate) for oral suspension for the treatment of patients with UCDs in early-to-mid Q3 2022.

“While the outcome of the NDA review was not what we had hoped for, multiple rounds of labeling negotiations have already been conducted to date and we believe the recommendations raised by FDA can be appropriately addressed. We should be able to resubmit the NDA relatively quickly,” said Chris Schelling, CEO and Founder of Acer. “We remain committed to bringing a new treatment option to patients in the U.S. with UCDs.”

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 will be able to meet its intended resubmission timeline for the NDA, that FDA inspection of the third-party contract packaging manufacturer facility will be satisfactory, that such inspection is the only impediment to FDA approval of a resubmitted NDA, that a resubmitted NDA will otherwise be approved by the FDA, or 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 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 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). Relief also continues to study aviptadil for several possible lung related conditions. Finally, 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 RLTF and RLTY. For more information, visit www.relieftherapeutics.com Follow Relief on [LinkedIn](#).

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 investigational product candidates to safely and effectively treat diseases and to be approved for marketing; our ability to submit regulatory filings (including for ACER-001 for oral suspension for the treatment of patients with UCDs) within intended timeframes, to address satisfactorily the requirements for regulatory approval (including through FDA inspection of our third-party contract packaging manufacturer for ACER-001 for oral suspension for the treatment of patients

with UCDs), or to otherwise address satisfactorily the requirements for and to obtain regulatory approval (including approval by the FDA of a resubmitted NDA for ACER-001 for oral suspension for the treatment of patients with UCDs); our ability to close upon and obtain the proceeds of any financing arrangements as well as to satisfy the ongoing conditions and requirements for maintaining the financing facilities and avoiding default or an accelerated payment requirement; 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 product candidates; 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. 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) whether the FDA will approve Acer's NDA for ACER-001, (ii) whether RELIEF THERAPEUTICS Holding SA will submit an application for approval of ACER-001 in Europe and the timing of filing such application, (iii) whether any such application submitted to European authorities seeking marketing authorization for ACER-001 for the treatment of patients 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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