

Ad hoc announcement pursuant to Art. 53 LR

Relief Therapeutics Announces That Its Collaboration Partner, Acer Therapeutics, was Issued U.S. Patent 11,202,767 Covering ACER-001 Methods of Use for the Treatment of Urea Cycle Disorders and Maple Syrup Urine Disease

Geneva, Switzerland, February 1, 2022 – RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLTF, RLFTY) (“Relief”), a biopharmaceutical company seeking to provide patients therapeutic relief from serious diseases with high unmet need, today announced that its collaboration partner, Acer Therapeutics, has been issued a new patent from the U.S. Patent and Trademark Office (USPTO) for certain claims related to ACER-001 (sodium phenylbutyrate). Specifically, patent 11,202,767 covers methods of use claims related to ACER-001’s multi-particulate dosage formulation for oral administration as a potential treatment for Urea Cycle Disorders (UCDs) and Maple Syrup Urine Disease (MSUD). These claims are in addition to the previously reported issuance of patent 11,154,521, which covers pharmaceutical composition claims of ACER-001. Both patents have an expiration date in 2036. Acer Therapeutics’ New Drug Application (NDA) for ACER-001 to treat UCDs is currently under U.S. Food and Drug Administration (FDA) review, with a Prescription Drug User Fee Act (PDUFA) target action date of June 5, 2022.

“Our collaboration partner, Acer Therapeutics, continues to solidify their intellectual property portfolio for ACER-001,” stated Raghuram (Ram) Selvaraju, Chairman of Relief. “We believe this coated formulation of sodium phenylbutyrate could be an important treatment for patients with UCDs and we hope to extend its use as a potential treatment for MSUD and other indications. In the meantime, Relief remains focused on submitting a Marketing Authorization Application for ACER-001 for the treatment of patients with UCDs in Europe.”

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.

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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*³, 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 aversive taste and odor⁴, frequency with which medication must be taken, required number of pills, and the high cost of the medication.

About ACER-001

ACER-001 (sodium phenylbutyrate) is being developed for the treatment of various inborn errors of metabolism, including UCDs and 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's multi-particulate dosage formulation for oral administration is designed to minimize the aversive taste and odor⁴ of sodium phenylbutyrate while quickly dissolving in the stomach. The ACER-001 NDA for UCDs is currently under FDA review with a PDUFA target action date of June 5, 2022. ACER-001 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.

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.
4. Peña-Quintana L, et al. Profile of sodium phenylbutyrate granules for the treatment of urea-cycle disorders: patient perspectives. *Patient Prefer Adherence.* 2017 Sep 6;11:1489-1496.

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 through Relief's collaboration partner in the U.S., NeuroRx, Inc. 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

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formulation of sodium phenylbutyrate (NaPB) for the treatment of Urea Cycle Disorders and Maple Syrup Urine Disease. Finally, 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.

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.

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CONTACT:

RELIEF THERAPEUTICS Holding SA

Jack Weinstein

Chief Financial Officer and Treasurer

contact@relieftherapeutics.com

FOR MEDIA/INVESTOR INQUIRIES:

Rx Communications Group

Michael Miller

+1-917-633-6086

mmiller@rxir.com

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 any application submitted to European authorities seeking marketing authorization for ACER-001 for the treatment of patient in Europe with UCDs will be approved, and (iii) those other risks, uncertainties and factors described in RELIEF THERAPEUTICS Holding SA's press releases and 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.