

## PRESS RELEASE

### Relief Reports 2020 Financial Results and Provides Business Update

**Geneva, Switzerland, April 15, 2021** – RELIEF THERAPEUTICS Holding AG (SIX: RLF, OTCQB: RLTF) ("Relief" or the "Company"), a biopharmaceutical company with its lead compound RLF-100™ (aviptadil) in advanced clinical development to treat COVID-19 induced lung injury, today announced its 2020 financial results for the year ended December 31, 2020 and provided a business update.

"The past year has been an incredibly productive and rewarding one for all of us at Relief," said **Raghuram (Ram) Selvaraju, Chairman of the Board**. "We have had an opportunity to make a true difference in fighting the ongoing COVID-19 pandemic with the development of RLF-100™ to treat critically ill patients. With the goal of bringing this potential treatment to patients as expeditiously as possible, we entered into important partnerships and made key hires, adding executives to our team who have strong expertise in important areas such as clinical development, regulatory and commercialization."

He continued: "Critical for the future growth of our Company, we also have taken a very important first step to broaden our development pipeline. We entered into a collaboration and license agreement for ACER-001, a compound in late-stage development for orphan diseases where patients are in need of better treatment options. We plan to continue to advance the development of our current programs and further grow our pipeline in the year ahead. I am excited about Relief's future as we work to provide patients with therapeutic relief in serious diseases with high unmet medical need."

#### **Recent Key Development and Corporate Highlights:**

##### ***Clinical Development Highlights (RLF-100)***

- In March 2020, a U.S. phase 2b/3 trial of RLF-100 (IV) for the treatment of patients with critical COVID-19 with respiratory failure commenced.
- In June 2020, RLF-100 (IV) was awarded Fast Track designation by the U.S. FDA for the treatment of acute lung injury (ALI) /acute respiratory distress syndrome (ARDS) associated with COVID-19.
- In July 2020, the FDA granted Expanded Access Protocol (EAP) designation for the treatment of respiratory failure induced by COVID-19 with RLF-100 (IV). Treatment was made available to patients who had exhausted standard therapies and were not eligible for the phase 2b/3 trial due to confounding medical conditions. Data from the first 21 patients in the EAP showed promising results demonstrating that some critically ill patients with COVID-19 experienced substantial clinical improvement when treated with RLF-100.
- In January 2021, Relief, its partner NeuroRx, and the Quantum Leap Healthcare Collaborative (QLHC) of San Francisco announced that NeuroRx and QLHC had signed a Clinical Trial Participation Agreement for the inclusion of inhaled RLF-100 in the I-SPY COVID-19 Clinical Trial. Quantum Leap is the sponsor of the I-SPY COVID-19 Trial, a platform trial that is assessing multiple drugs for the treatment of patients with critical COVID-19 who are hospitalized or in intensive care units.
- In January 2021, Relief and AdVita Lifescience GmbH signed a binding term sheet for Relief to acquire all shares of AdVita. Relief will gain access to all AdVita assets including future pending IP rights that may cover RLF-100 inhaled formulation specifications for the potential application of inhaled aviptadil in the treatment of lung diseases such as ARDS and Pulmonary Sarcoidosis.

## PRESS RELEASE

- In February 2021, Relief's partner NeuroRx announced the initiation of a U.S. phase 2b/3 trial evaluating inhaled RLF-100 in patients with moderate to severe COVID-19 in order to prevent progression to respiratory failure.
- In March 2021, Relief's partner NeuroRx reported topline results (28-day and 60-day) from the U.S. phase 2b/3 trial evaluating RLF-100 (IV) for the treatment of patients with critical COVID-19 with respiratory failure. On the basis of the findings, NeuroRx plans to apply to the U.S. FDA for Emergency Use Authorization (EUA) and subsequently plans to submit a New Drug Application (NDA).
- In March 2021, NeuroRx announced that RLF-100 had been selected for inclusion in TESICO (Therapeutics for Severely Ill Inpatients with COVID-19), a phase 3 multicenter clinical trial that will include the United States and multiple foreign countries, that is being sponsored by the U.S. National Institutes of Health (NIH).

### *Corporate Highlights*

- To match the fast pace at which the Company is developing, Relief strengthened its management team during 2020 and early 2021 with the additions of Jack Weinstein as Chief Financial Officer and Treasurer, Chris L.J.J. Stijnen as Chief Commercial Officer, Gilles Della Corte, M.D. as Chief Medical Officer, J. Paul Waymack, M.D., Sc.D. as development and regulatory consultant and J.J. Scherpbier of Sonsbeek Pharma Consultancy B.V. as manufacturing and supply chain consultant.
- To strengthen and expand its pipeline, in March 2021, Relief signed a Collaboration and License Agreement with Acer Therapeutics for the worldwide development and commercialization of ACER-001 for the treatment of Urea Cycle Disorders (UCDs) and Maple Syrup Urine Disease (MSUD).

### *Financial Highlights*

#### **2020**

- Relief reported a strong financial position with CHF 43.1 million in cash on its balance sheet as of December 31, 2020 (CHF 0.1 million at year end 2019).
- Service expenses were CHF 13.7 million (2019: CHF 0.1 million), primarily for services provided by collaboration partner NeuroRx, Inc. and other third parties related to RLF-100 clinical trials.
- Personnel expenses were CHF 2.6 million (2019: CHF 0.3 million), as additional human resources were essential to oversee clinical trial activities with RLF-100 and to strengthen Relief's organization.
- Other administrative expenses were CHF 3.0 million (2019: CHF 0.6 million), as requirements for legal, consulting and marketing services increased in conjunction with the Company's activities.
- Relief recognized a one-time disposal gain of CHF 3.4 million following the divestment of its former subsidiary holding the atexakin alpha compound.
- EBITDA for 2020 was a loss of CHF 20.3 million (2019: loss of CHF 0.9 million).
- Net loss in 2020 was CHF 7.8 million (2019: CHF 7.5 million).
- In July 2020, Relief entered into a binding agreement with Gem Global Yield LLC (GEM) for the redemption of the outstanding CHF 1.7 million debt position in exchange for newly issued Relief shares.
- Through 2020, Relief successfully closed several capital increases in the amount of CHF 49.2 million pursuant to drawdowns from its Share Subscription Facility ("SSF") in place with GEM.
- Financing activities throughout 2020 resulted in the raising of a total of CHF 58 million in new equity financing.

## PRESS RELEASE

### *Post reporting period*

- In January 2021, Relief signed a second binding agreement with GEM for the implementation of a new SSF in the amount of up to CHF 50 million.
- In March 2021, the Company raised CHF 10 million in a private placement with a single healthcare-dedicated U.S. institutional investor.
- As of April 15, 2021, the Company had available cash of approximately CHF 35 million.

**Jack Weinstein, Chief Financial Officer and Treasurer of Relief**, commented: “Relief is not the same company it was a month ago, let alone a year ago. Through exercising flexible financing tools, which allows the Company to support ongoing clinical development of RLF-100, ACER-001 and its pipeline expansion strategy, we have developed a cash runway that will see us well into 2022. I remain excited about meeting the challenges of growing a biopharmaceutical company with a very bright future.”

### **Outlook for 2021:**

Relief expects to make continued progress with its development programs and in advancing its business in the months ahead.

### **Pipeline**

Looking first to RLF-100 (IV), as our partner NeuroRx executes plans to file for EUA for the treatment of critically ill patients with COVID-19, followed by an NDA, Relief is preparing for clinical assessment and potential commercialization in Europe and other territories. Once Relief has received and analyzed the full data set from the U.S. phase 2b/3 trial, the Company will decide on the best path forward for the development of RLF-100 in Europe and other territories.

Turning to RLF-100 (inhaled), the acquisition of AdVita is expected to close in Q2 2021. Additionally, Relief is hopeful that its partner NeuroRx will have results from the ongoing U.S. phase 2b/3 trial evaluating inhaled RLF-100 in H2 2021.

Our second late-stage program in collaboration with Acer Therapeutics for ACER-001 is expected to progress quickly in 2021. A pre-NDA meeting is scheduled to occur between Acer and the FDA in Q2 2021 to discuss the results of the clinical study of ACER-001 in UCDS. Provided no additional data are requested by FDA during the meeting and ongoing development activities are successfully completed, Acer expects to submit a 505(b)(2) NDA for ACER-001 for the treatment of UCDS in mid-2021, with a potential regulatory decision in H1 2022. Relief plans to initiate discussions with European regulatory authorities regarding ACER-001 in UCDS in Q3 2021. Clinical studies in MSUD could start later in 2021.

Relief plans to continue its strategy to aggressively pursue opportunities to expand its pipeline with attractive late-stage clinical assets that would drive the evolution of the Company into a mature, diversified biopharmaceutical company.

### **Corporate**

Adding expertise by hiring personnel and consultants will continue in an effort to match the Company’s pace of development.

Throughout 2021 Relief will continue to evaluate and take steps to facilitate interest from institutional investors. In addition, the Company expects to “up list” to a major U.S. stock exchange in the coming months.

## PRESS RELEASE

Relief's 2020 Annual Report is available for download at <https://relieftherapeutics.com/investor-relations>.

###

### 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](http://www.relieftherapeutics.com).

Follow us on [LinkedIn](#)

### CONTACT

#### RELIEF THERAPEUTICS Holding AG

Raghuram (Ram) Selvaraju, Ph.D., MBA

Chairman of the Board

Mail: [contact@relieftherapeutics.com](mailto:contact@relieftherapeutics.com)

### FOR MEDIA/INVESTOR INQUIRIES:

#### MC Services AG

Anne Hennecke / Brittney Sojeva

Tel.: +49 (0) 211-529-252-14

Mail: [relief@mc-services.eu](mailto:relief@mc-services.eu)

Disclaimer: 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.