Ad hoc announcement pursuant to Art. 53 LR

Relief Therapeutics Announces Positive 12-Month Stability Data for Inhaled and Intravenous Preparations of RLF-100® (Aviptadil Acetate)

Relief to file a revised provisional patent application for RLF-100® based on the new stability results

GENEVA (April 17, 2023) – RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLFTF, RLFTY) (Relief Therapeutics, or Relief), a biopharmaceutical company committed to delivering innovative treatment options with the potential for transformative outcomes to benefit those suffering from select specialty and rare diseases, today announced positive 12-month stability data for the liquid and lyophilized preparations of RLF-100®, intended for intravenous (IV) and inhaled administration. RLF-100® is the company's proprietary, investigational formulation of aviptadil acetate.

The data from the stability study showed that both inhaled and IV RLF-100® demonstrated high purity levels at 12 months at all temperatures tested, including refrigerated and room temperature environments. The results are consistent with prior data observed at three- and six-month intervals. The stability testing study will continue to determine the maximum shelf life of RLF-100®.

Based on the latest results, Relief Therapeutics intends to amend its previously filed provisional patent application for RLF-100® with the new findings. If granted, this patent could provide exclusivity for RLF-100® at least until 2042, without considering Hatch-Waxman extensions or other patent term adjustments. The Hatch-Waxman Act permits a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process.

"The testing conducted to date has consistently shown that our novel, optimized composition of aviptadil acetate provides better stability results in both the liquid and lyophilized preparations. RLF-100® was shown to be shelf stable and active after one year at temperatures suitable for shipping and long-term storage. This is an important milestone toward commercialization to ensure that RLF-100® is safe and effective, no matter where in the world it is supplied." said Jack Weinstein, chief executive officer at Relief Therapeutics. "We believe this new, stable formulation has significant clinical and commercial value and our goal is to establish RLF-100® as the standard of care for the prevention and treatment of respiratory failure and its complications in both the acute and chronic applications."

Stability testing of pharmaceutical products is mandatory for regulatory approvals. If a product fails to meet the standards prescribed by regulatory authorities, the product will not be granted approval for commercialization. Planning, execution and completion of studies in given timelines plays a major role in securing approval and ensuring a product reaches patients who need it.

RLF-100® is under development for the potential treatment of acute and chronic lung diseases, including pulmonary sarcoidosis, infectious acute respiratory distress syndrome (ARDS), checkpoint inhibitor-induced pneumonitis (CIP) and chronic berylliosis. The U.S. Food and Drug Administration (FDA) granted RLF-100® Orphan Drug designation (ODD) to inhaled RLF-100® for the potential treatment of pulmonary sarcoidosis in August 2021.

About Drug Stability Requirements

The purpose of long-term and accelerated stability testing is to determine how long a drug product will maintain the properties and characteristics, such as purity, efficacy and structure, it possessed at the time of manufacture as well as the quality of a drug product over time while under the influence of environmental conditions such as temperature, humidity and light. Under long-term and accelerated stability storage conditions, the drug is evaluated by high performance liquid chromatography (HPLC) to separate, identify and quantify each chemical component to a very high degree of resolution to assess if any changes occur in the chemical composition. Stability studies are conducted during all phases of drug development to satisfy the regulatory requirements for clinical trials. Data from these studies is then used to establish recommended storage conditions, retest intervals and shelf life. Demonstrating long-term stability of a drug to be used in human clinical testing is essential to prove the potency and efficacy of the drug is not affected during prolonged shelf life. Long-term stability is completed over three years, with reporting at 0, 3, 6, 9, 12, 18, 24 and 36 months. Accelerated stability is completed over six months, with reporting at 0, 3 and 6 months.[1,2]

About RLF-100® (aviptadil acetate)

Aviptadil acetate is a synthetic form of vasoactive intestinal peptide (VIP) comprising 28 amino acids, which was first discovered in 1970. Although initially identified in the intestinal tract, human VIP is now known to be produced throughout the body and primarily concentrated in the lungs. VIP has shown a multimodal mechanism of action: decrease of inflammatory cytokines release leading to prevention of cytokine storm syndrome and viral replication, immunomodulating effect, vasodilating and bronchodilating effects and prevention of surfactant depletion. Seventy percent of VIP in the body is bound to a less common type of cell in the lung, the alveolar epithelial type II (AT2) cell, which is critical to the absorption of oxygen into the body. Aviptadil acetate has a 20-year history of safe use in humans in multiple human trials for sarcoidosis, idiopathic pulmonary fibrosis, asthma, pulmonary arterial hypertension and sepsis-induced acute respiratory distress syndrome. For example, a combination of aviptadil with phentolamine is approved for the treatment of erectile dysfunction by intra-cavernous injections in countries outside the U.S. In early 2022, an unrelated pharmaceutical company in India received emergency use approval for its own formulation of aviptadil for the treatment of COVID-19 from the Drugs Controller General of India. While their approval does not affect the application for approval of our formulation in other countries, it substantiates our original hypothesis that RLF-100 is a potentially viable treatment for COVID-19-related ARDS.

About Relief Therapeutics

Relief Therapeutics is a commercial-stage biopharmaceutical company committed to advancing treatment paradigms and delivering improvements in efficacy, safety and convenience to benefit the lives of patients living with select specialty and rare diseases and disorders. Relief Therapeutics' portfolio offers a balanced mix of marketed, revenue-generating products, our proprietary, globally patented Physiomimic™ and TEHCLO™ drug delivery platform technologies and a highly targeted clinical development pipeline consisting of risk-mitigated assets to address rare metabolic disorders, rare skin diseases and rare respiratory diseases. In addition, Relief Therapeutics is commercializing several legacy products via licensing and distribution partners. Our mission to provide therapeutic relief to those suffering from rare diseases and disorders is being advanced by an international team of well-established, experienced biopharma industry leaders with extensive research, development and rare disease expertise. Relief Therapeutics' headquarters are in Geneva, with additional offices in Balerna, Switzerland, Offenbach am Main, Germany and Rome. Relief Therapeutics 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, please visit our website at www.relieftherapeutics.com or follow Relief Therapeutics on LinkedIn and Twitter.

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This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties, and other factors, which could cause the actual results, financial condition, performance or achievements of Relief Therapeutics to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. A number of factors, including those described in Relief Therapeutics' filings with the SIX Swiss Exchange and the U.S. Securities and Exchange Commission (SEC), could adversely affect Relief Therapeutics. Copies of Relief Therapeutics' filings with the SEC are available on the SEC EDGAR database at www.sec.gov. Relief Therapeutics does not undertake any obligation to update the information contained herein, which speaks only as of this date.

REFERENCES

[1] International Council for Harmonisation (ICH). Technical Requirements for Pharmaceuticals for Human Use. Quality Guidelines: Q1A - Q1F Stability. Available at: https://www.ich.org/page/quality-guidelines. Accessed on April 14, 2023.

[2] U.S. Food and Drug Administration, Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). May 2021. Guidance For Industry: Pharmaceutical Quality/Chemistry, Manufacturing & Controls (PQ/CMC). Available at: https://www.fda.gov/industry/fda-data-standards-advisory-board/pharmaceutical-qualitychemistry-manufacturing-controls-pqcmc. Accessed on April 14, 2023.