

## Ad hoc announcement pursuant to Art. 53 LR

Relief Reports Regulatory Clearance in Germany to Commence a Multicenter, Double-blind, Randomized Phase 2 Clinical Trial to Evaluate Inhaled Aviptadil for the Treatment of Sarcoidosis

**Geneva, Switzerland, September 2, 2021** – RELIEF THERAPEUTICS Holding SA (SIX: RLF, OTCQB: RLFTF) ("**Relief**"), a biopharmaceutical company seeking to provide patients therapeutic relief from serious diseases with high unmet need, reported today that its recently acquired German subsidiary, AdVita Lifescience GmbH ("**AdVita**"), has received regulatory clearance to commence a phase 2 clinical trial in Germany to evaluate inhaled aviptadil for the treatment of sarcoidosis.

Following a proof-of-concept trial in 20 sarcoidosis patients which demonstrated the suppression of inflammatory mechanisms of the lung in combination with amelioration of dry cough and exertional dyspnea, AdVita received clearance by the German medical regulatory authority Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) to conduct a randomized, double-blind, multicenter clinical trial in sarcoidosis patients.

Raghuram Selvaraju, Chairman of the Board of Relief, commented, "Receiving regulatory clearance to begin a phase 2 clinical trial of inhaled aviptadil marks another clinical milestone for Relief and our subsidiary, AdVita. Aviptadil is believed to be the only known experimental drug that could potentially suppress sarcoidosis-associated cough, one of the major symptoms reducing quality of life in this patient population. We look forward to initiating this trial and to further exploring the clinical utility of aviptadil across multiple pulmonary indications."

## **ABOUT SARCOIDOSIS**

Sarcoidosis is a rare disease in which the inflammatory process involves the alveoli (air sacs), small bronchi, and small blood vessels. As sarcoidosis progresses, small lumps, or granulomas, appear in the affected tissues which tend to remain inflamed and become scarred (fibrotic). Granulomas are structured masses composed of activated immunological cells (macrophages, lymphocytes, mast cells and fibroblasts). Many Sarcoidosis patients are left with permanent lung damage as they undergo a chronic course where complications such as pulmonary fibrosis are common and irreversible. Sarcoidosis affects up to about 100,000 people in the European Union, and a similar or higher amount in the U.S.



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## **ABOUT RELIEF**

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- $100^{TM}$  (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. In addition, Relief's recently completed acquisitions of APR Applied Pharma Research SA and AdVita Lifescience GmbH, brings 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 symbol RLFTF. For more information, visit <a href="www.relieftherapeutics.com">www.relieftherapeutics.com</a>. Follow us on **LinkedIn**.

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