

Ad hoc announcement pursuant to Art. 53 LR

Relief Announces Receipt of U.S. FDA Orphan Drug Designation for the use of RLF-100 (aviptadil) in the Treatment of Sarcoidosis

Relief now has Orphan Drug Designations for Its Sarcoidosis, Epidermolysis Bullosa (EB) and Phenylketonuria (PKU) Product Candidates

Geneva, Switzerland, August 3, 2021 – RELIEF THERAPEUTICS Holding AG (SIX: RLF, OTCQB: RLTF) (“Relief” or the “Company”), a biopharmaceutical company seeking to provide patients therapeutic relief from serious diseases with high unmet need, reported today that, via its newly acquired subsidiary, AdVita Lifescience GmbH, the Company has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (“FDA”) for RLF-100 (aviptadil), an inhaled formulation in development for the treatment of sarcoidosis. RLF-100 is a synthetic form of vasoactive intestinal peptide. In open label exploratory clinical experience in sarcoidosis patients, RLF-100 has been shown to be well tolerated and safe, and to produce favorable immunoregulatory effects in the lungs that have been associated with symptom relief in a significant proportion of the patients.

“Receipt of our third Orphan Drug Designation is another important milestone for the Company, as it underscores the potential strength of our pipeline and the high need for better treatments for rare diseases such as sarcoidosis,” stated Raghuram (Ram) Selvaraju, Chairman of the Board of Directors of Relief. “The timing of this newest Orphan Drug Designation comes on the heels of our just closed acquisition of AdVita Lifescience GmbH and supplements those we have for our drug candidates for EB and PKU, which we added to our pipeline through our recent acquisition of APR Applied Pharma Research SA, consistent with our strategy to become a fully integrated diversified commercial-stage pharmaceutical company.”

Orphan Drug Designation is granted for products that are intended to treat life-threatening or chronically debilitating conditions affecting less than 200,000 patients in the U.S. and no more than five in 10,000 persons in the European Union. Further criteria include the potential of the product to provide significant patient benefit over available treatment, or to fill an unmet medical need where no treatment exists.

Orphan Drug Designation confers numerous benefits to the development of new products, including clinical protocol assistance and, upon marketing authorization, assures marketing exclusivity for a period of up to seven years in the U.S. and up to ten years in the EU once the medicine is on the market.

About Sarcoidosis

Sarcoidosis is a rare disease in which the inflammatory process involves the alveoli (air sacs), small bronchi, and small blood vessels. As the disease 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 immune 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. Currently there are about 140,000 sarcoidosis patients 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™ (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 bring a diverse pipeline of marketed and development-stage programs.

RELIEF THERAPEUTICS Holding AG is listed on the SIX Swiss Exchange under the symbol RLF and is quoted in the U.S. on OTCQB under the symbol RLFTF. For more information, visit www.relieftherapeutics.com. Follow us on [LinkedIn](#).

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