CLINICAL PHASE II LICENSING OPPORTUNITY

INTERFERON GAMMA

SAFETY & EFFICACY
• Regulatory approved drug for Chronic Granulomatous Disease, Severe Malignant Osteopetrosis, Tuberculosis, Rheumatic Arthritis, Myeloid Leukemia via injection, with excellent safety profile.
• Molecular Mode of Action defined and validated, with pre-clinical and clinical Proof of Concept validation in Idiopathic Pulmonary Fibrosis (IPF).
• Pharmacokinetics / Pharmacodynamics relationship & therapeutic window demonstrated in IPF.
• When applied correctly as inhalative, precision medicine drug, statistically significant improvement in lung function.

ADVANTAGES
• Interferon γ is a crucial human anti-fibrotic factor; it is severely diminished in IPF patients, and this absence is one of the major reasons for IPF pathology.
• Our issued patent, Orphan Drug Designations in the USA and European Union, and know-how follow exactly the Precision medicine definition for a drug treatment:
  a) National Academy of Sciences: “Use of genomic, epigenomic, exposure and other data to define individual patterns of disease, potentially leading to better individual treatment.”
  b) FDA: “Typically, a diagnostic device, and a therapeutic product – to improve patient outcomes.”
  c) EU: “Providing the right treatment to the right patient at the right dose at the right time.”

PRECISION MEDICINE DRUG FOR IDIOPATHIC PULMONARY FIBROSIS

PEAK GLOBAL SALES POTENTIAL IN EXCESS OF $2.5 Billion
MARKETING APPROVAL EXPECTED IN AROUND 4 YEARS

CLINICAL DEVELOPMENT
• Novel endpoint developed. Sample size of 60 patients allows for randomized, controlled approval trial with 90% power to reach statistical significance.

PATENTS & AND OMPD
• Issued patent for Europe, valid until 2022, with SPC 2027.
• Orphan Drug Designation granted in the US and EU by the FDA and European Union.

Relief Therapeutics is seeking partners for the US and European commercialization of inhaled Interferon Gamma in IPF.

IDIOPATHIC PULMONARY FIBROSIS - IPF
• IPF is a devastating, progressive illness of the lung, with a median survival time of only a few years after the onset of symptoms. IPF is a form of interstitial lung diseases (ILD). In ILD, healthy tissue is progressively replaced by components of the connective and supporting tissue. This process is based on tissue repair, which would normally accomplish regular wound healing, but in an exaggerated way, thus, scar formation replaces organ tissue until complete loss of organ function may occur. Regulatory approved drugs: Pirfenidone, Nintedanib.
• Prevalence 27 / 100,000 (Orphanet).
• 154,000 patients in Europe (European Medicines Agency 2013).
• 132,000 patients in the USA (Boehringer Ingelheim 2014).