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PRESS RELEASE

APEPTICO has signed the Grant Agreement with the European Commission for the accelerated development and clinical use of the development compound *SOLNATIDE* for the treatment of COVID-19 patients

Vienna, Austria, 1st April, 2020: APEPTICO Forschung und Entwicklung GmbH today announced that it has signed, together with the "solnatide consortium", the Grant Agreement with the European Commission to accelerate the process of making APEPTICO's proprietary investigational medicinal product (IMP) *solnatide* available for medical treatment of patients severely affected by the novel coronavirus 2019 (SARS-CoV-2) disease, COVID-19.

APEPTICO is a privately-held biotechnology company based in Austria, developing peptide-based medicinal products to treat life-threatening pulmonary dysfunctions, such as severe respiratory failure, oedematous respiratory failure (lung oedema), acute respiratory distress syndrome (ARDS), primary graft dysfunction (PGD) following lung transplantation, high altitude pulmonary oedema (HAPE) and pseudohypoaldosteronism type 1B (PHA1B).

APEPTICO's lead compound, the therapeutic molecule *solnatide* (INN) is being developed by APEPTICO for the treatment of various forms of life-threatening acute pulmonary dysfunction and pulmonary oedema in ARDS patients. In 2013, APEPTICO successfully completed a phase I clinical study in healthy subjects, proving the safety of *solnatide*. APEPTICO subsequently successfully completed two phase II clinical studies, one a randomized, double-blinded placebo-controlled trial using inhaled *solnatide* in mechanically-ventilated ARDS patients with lung oedema, the other a randomized, placebo-controlled pilot study in patients suffering from primary graft dysfunction (PGD) following lung transplantation.

Clinical data gathered so far from hospitalised patients suffering from COVID-19 have revealed that 20% suffer from ARDS and the involvement of pulmonary oedema is evidenced by post-mortem sampling of a patient who succumbed to COVID-19 infection. The observed mortality rate for ARDS is 20-30%. At present no medicine has been approved specifically for the therapeutic treatment of pulmonary permeability oedema or ARDS.

The Grant Agreement was made available via the Horizon2020 programme "Advancing knowledge for the clinical and public health response to the 2019-nCoV epidemic" (https://ec.europa.eu/commission/presscorner/detail/en/ip_20_386).

In this emergency situation in hospitals across Europe, APEPTICO will make *solnatide* IMP available for the acute and therapeutic treatment of patients suffering from severe symptoms of infection with the **SARS-CoV-2** novel coronavirus.

Commenting on the EU Grant Agreement, Bernhard Fischer, CEO of APEPTICO, stated: "We are very happy that the European Commission agreed with APEPTICO and the "solnatide-consortium" to financially support us in the consortium's effort to make *solnatide* IMP available for the treatment of severely affected patients with the new coronavirus. By offering our *solnatide* IMP for the immediate treatment of patients, APEPTICO commits its responsibilities towards the society."

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About APEPTICO

APEPTICO Forschung und Entwicklung GmbH ("APEPTICO") is a privately-held development stage biotechnology company with office in Vienna, Austria, developing peptide-based products targeting life-threatening pulmonary diseases, including oedematous respiratory failure, acute lung injury, primary graft dysfunction, high altitude pulmonary oedema and PHA type 1. The peptide molecules correspond to validated, pharmacodynamic active structures and domains of proteins and biopharmaceuticals. By concentrating on synthetically produced protein structures APEPTICO avoids general risks associated with gene- and cell-technologies. APEPTICO makes use of its technology platforms PEPBASE(TM) and PEPSCREEN(TM) to significantly reduce cost and to shorten time to market.

About solnatide

Solnatide (laboratory code AP301) is a synthetic molecule whose structure is based on the lectin-like domain of human Tumour Necrosis Factor alpha. Solnatide is water soluble and can be administered as aerosol (small droplets of diameter 3 μm or less) directly into the lungs of patients by oral inhalation. Solnatide IMP has been designed for activation of the pulmonary epithelial sodium channel (ENaC) and for the restoration of the injured endothelial-epithelial barrier of pulmonary alveoli.

APEPTICO's investigational compound *solnatide* (INN) was originally designed for the therapeutic treatment of patients with Acute Respiratory Distress Syndrome (ARDS) and various forms of life-threatening pulmonary permeability oedema (PPO). Orally inhaled solnatide IMP has completed a first-in-man (FIM) Phase I clinical study (EUDRACT No. 2011-000223-33), and has delivered clinical proof-of-concept in a randomised, placebo-controlled, double-blinded Phase II clinical study (EUDRACT No. 2012-001863-64) as well as in a Phase II pilot study (EUDRACT No. 2013-000716-21) in patients suffering from pneumonia, sepsis, ARDS, Primary Graft Dysfunction, and other causes of life-threatening pulmonary dysfunction.

Solnatide IMP has been designated an orphan medicinal product in the European Union for the therapeutic indication "Treatment of Acute Lung Injury (ARDS)".

About the consortium

For the "solnatide project", APEPTICO has formed a consortium of leading European companies from Germany, Italy, Austria and Spain, to continue and speed up the manufacturing process of *solnatide*, as well as the immediate employment of *solnatide* IMP for clinical use.

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