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PRESS RELEASE

SOLNATIDE has been approved by the Austrian Federal Office for Safety in Health Care for the treatment of COVID-19 patients with severe pulmonary dysfunction

Vienna, Austria, 07th April, 2020: APEPTICO Forschung und Entwicklung GmbH today announced that its *solnatide* IMP has been approved for Compassionate Use by the Austrian Federal Office for Safety in Health Care (BASG) for the treatment of patients infected by the novel coronavirus SARS-CoV-2 and subsequently developing severe pulmonary dysfunction (severe COVID-19).

APEPTICO is a privately-held biotechnology company from Vienna/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).

Clinical data gathered so far from hospitalised patients suffering from COVID-19 have revealed that 20% suffer from life-threatening pulmonary dysfunctions such as ARDS (acute respiratory distress syndrome), and the involvement of pulmonary oedema is evidenced by post-mortem sampling of patients who succumbed to COVID-19 infection. The observed mortality rate for ARDS ranges from 16% to 60%. At present no medicine has been approved specifically for the therapeutic treatment of ARDS, pulmonary permeability oedema, as well as ARDS in COVID-19 patients.

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.

Commenting on the approval of *solnatide* by the Austrian Federal Office for Safety in Health Care (BASG), Bernhard Fischer, CEO of APEPTICO, stated: "In this emergency situation, we have submitted all relevant data to the BASG for review. We are very honoured that the BASG has approved *solnatide* for the treatment of severely injured COVID-19 patients. According to our records this is a first-time approval of an innovative drug from Austria for the treatment of SARS-CoV-2 induced acute lung dysfunction (ARDS) in severely affected COVID-19 patients. APEPTICO will continue taking its social responsibility in the fight against the novel coronavirus", he added.

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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)".

Involvement of ARDS in severe cases of COVID-19

ARDS plays a major, if not the major role in the morbidity and mortality on COVID-19 patients. Acute respiratory distress syndrome (ARDS) is characterized by acute lung injury, noncardiogenic pulmonary oedema and severe hypoxia. Several studies reporting the clinical progression and characteristics in hospitalized COVID-19 patients have focussed on the prevalence of ARDS amongst these patients and particularly amongst the more severe cases. From these studies we see that one fifth to one third of hospitalized COVID-19 patients developed ARDS. One fifth to one third of hospitalized patients suffering from COVID-19 required transfer to the ICU unit. Amongst COVID-19 patients requiring ICU treatment approximately two thirds suffer from life-threatening ARDS. Estimates of the mortality rate amongst COVID-19 ICU patients ranges from 16.7% to 61%-

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