



APEPTICO Forschung & Entwicklung
Mariahilferstraße 136
1150 Vienna, Austria



OPIS Headquarters
Via Matteotti 10
20832 Desio, Italy

PRESS RELEASE

SOLNATIDE has been approved for the treatment of COVID-19 patients suffering from pulmonary oedema and acute respiratory distress syndrome by the Italian Medicines Agency and the Ethics Committee of the National Institute for Infectious Diseases (Lazzaro Spallanzani-Rome)

Vienna/Austria, Desio/Italy, 28th April 2020: APEPTICO Forschung und Entwicklung GmbH and OPIS srl today announced that the *solnatide* IMP has been approved within the compassionate use program of drugs undergoing clinical trials for treatment of COVID-19 patients suffering from pulmonary permeability oedema and acute respiratory distress syndrome (ARDS) by the Italian Medicines Agency and the Ethics Committee of the National Institute for Infectious Diseases Lazzaro Spallanzani.

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).

OPIS is a full-service Contract Research Organization (CRO) founded in 1998 in Italy, providing premium trial management for multi-country clinical trials, including state-of-the-art information technology solutions and innovative approaches to the increasing complexity and variety of current projects.

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. Previously, *solnatide* has been assessed for safety and tolerability in a phase I clinical study in healthy subjects, and for preliminary efficacy two phase II clinical studies in mechanically-ventilated patients with acute respiratory distress syndrome (ARDS) and in patients suffering from primary graft dysfunction (PGD) following lung transplantation.

Commenting on the approval of *solnatide* by the Italian Medicine Agency (Agenzia Italiana del Farmaco - AIFA) and the Italian National Ethics Committee, Bernhard Fischer, CEO of APEPTICO, stated: "After the initial approval in Austria, this is the second European country approving *solnatide* for the emergency treatment of severely injured COVID-19 patients. Together with OPIS we will make *solnatide* available for COVID-19 patient treatment in Italy, one of the European Countries most affected by the new coronavirus infections."

Aldo Poli, CEO of OPIS added: "We are proud to participate to the clinical development of *solnatide* in patient affected with COVID-19. At this time of great difficulty on a global level, OPIS is pleased to be at the forefront of the fight against coronavirus, collaborating with APEPTICO with the aim of providing a new therapeutic approach in patients with COVID-19 who develop respiratory complications."

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 OPIS

Founded in 1998 in Italy and now operating at international level, OPIS is a full service CRO providing premium trial management for multi-country clinical trials, including state-of-the-art information technology solutions and innovative approaches to the increasing complexity and variety of current projects. OPIS extensive expertise can cover all phases of drug related trials, with no restrictions to therapeutic area as well as clinical investigations for medical and diagnostic devices, Investigator Initiated Trials (IITs), and compassionate use programs.

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, and has delivered clinical proof-of-concept in a randomised, placebo-controlled, double-blinded Phase II clinical study as well as in a Phase II pilot study, in patients suffering from pneumonia, sepsis, ARDS, Primary Graft Dysfunction, and other causes of life-threatening pulmonary dysfunction. Currently, *solnatide* is subject to a Phase IIB clinical study in Austria and Germany for treatment of patients with moderate-severe ARDS. *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%.

Physicians interested in accessing to the compassionate use program with solnatide can contact OPIS at the following e-mail address:	To contact APEPTICO directly
solnatidecompassionateuse@opis.it	Prof. Dr. Bernhard Fischer, CEO APEPTICO Forschung und Entwicklung GmbH Mariahilferstraße 136, Top 1.1.5 1150 Vienna, Austria T: +43-664-1432919 F: +43-1-25330337795 E-mail: b.fischer@apeptico.com URL: www.apeptico.com