

PRESS RELEASE

Safety and tolerability of Solnatide have been confirmed in a Phase IIB clinical study in mechanically ventilated patients with pulmonary permeability oedema in ARDS

Vienna, Austria, 01.11.2025: APEPTICO, a privately held biotechnology company developing peptide drugs, today announced that the phase IIB clinical study of Solnatide confirmed safety and tolerability as well as efficacy, in the treatment of pulmonary permeability oedema in mechanically ventilated patients suffering from acute respiratory distress syndrome (ARDS).

Pulmonary oedema occurs when fluid leaks from the pulmonary capillary network into the lung interstitium and alveoli. Massive pulmonary permeability oedema is a major characteristic of severe acute respiratory distress syndrome (ARDS), a life-threatening condition with a mortality rate of around 35-45%, despite modern day care. Currently, there is no effective pharmacotherapy available for the treatment of pulmonary permeability oedema in patients having ARDS.

Solnatide (a.k.a. AP301, TIP peptide) is a small peptide designed to activate pulmonary oedema clearance in a variety of patients, including mechanically ventilated patients with ARDS or following lung transplantation. Solnatide opens the epithelial sodium ion channel (ENaC) and restores lung alveolar-capillary barrier function by mitigating protein kinase C- α activation and MLC phosphorylation, as well as by reducing reactive oxygen species generation. All of this improves lung tissue repair and pulmonary oedema clearance.

The Phase IIB clinical study “Safety and preliminary efficacy of sequential multiple ascending doses of Solnatide to treat pulmonary permeability oedema in patients with moderate-to-severe ARDS” was designed following recommendations from the FDA and was conducted in eleven clinical sites in Germany and Austria as a randomised, placebo-controlled, double-blind trial. In total, 91 patients with moderate to severe ARDS were treated with placebo or with three ascending doses of Solnatide. Solnatide was orally inhaled as a liquid aerosol every 12 hours for 7 days.

Results from this study showed that oral inhalation of Solnatide was equally safe as placebo and that TEAEs were reported with similar frequency in the placebo group as in the Solnatide groups. No Solnatide-treated patients died during the Solnatide treatment period of day 1 to day 7, although the predicted mortality rate for Solnatide patients, based on APACHE 2 score, was higher as compared with the patients in the placebo group. As observed before, Solnatide led to a more pronounced decrease of extravascular lung water as compared to the placebo group, and shortened the period between treatment and extubation. Ventilator-free days increased with increasing doses of Solnatide. These results suggest that Solnatide should be further evaluated in a larger patient cohort in a phase 3 clinical trial.

Dr. Bernhard Fischer, CEO of APEPTICO, stated: “We are relieved to have completed this significant clinical goal. Although the COVID 19 pandemic between 2019 and 2022 created a harsh environment for the participating hospitals, we could finally finish the patient treatment last year, which enabled us now to analyse the clinical data and to draw conclusions for the forthcoming Phase III trial”.

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About APEPTICO GmbH (www.apeptico.com)

APEPTICO is a privately-held biotechnology company based in Austria, developing peptide-based products targeting chronic and life-threatening diseases. The peptide molecules correspond to validated, pharmacodynamic active structures and domains of well-known 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 the Solnatide peptide family

Solnatide and derived peptides are synthetic molecules whose structures are based on structural elements of human proteins. The Solnatide peptide is water soluble and can be administered into the lung by oral inhalation. Formulated Solnatide is easily nebulised and the resulting aerosol is composed of peptide/water droplets of diameter 4 µm or less. Solnatide and derived peptides are designed for activation of the pulmonary epithelial sodium channel (ENaC). Activation of ENaC by Solnatide results in accelerated lung oedema clearance in the airspaces.

Comprehensive research and development conducted by APEPTICO in collaboration with the scientific team of Professor Dr. Rudolf Lucas (Medical College of Georgia at Augusta University, USA) and the scientific team of Professor Dr. Rosa Lemmens-Gruber (Department of Pharmacology and Toxicology, University Vienna, Austria) has demonstrated that Solnatide peptides are effective in various forms of pulmonary oedema, including pulmonary permeability oedema in ARDS resulting from pneumonia or sepsis, lung transplantation (primary graft dysfunction), as well as hydrostatic oedema and high altitude pulmonary oedema (HAPE).

APEPTICO's Solnatide has been granted orphan drug status for treatment of pulmonary permeability oedema in ALI/ARDS, for treatment of primary graft dysfunction following lung transplantation, and for treatment of high-altitude pulmonary oedema by the European Commission and European Medicines Agency (EMA), as well by the Food and Drug Agency (FDA).

About pulmonary oedema

Pulmonary oedema occurs when fluid leaks from the pulmonary capillary network into the lung interstitium and alveoli. There are many possible causes of lung oedema, such as heart failure (cardiac/hydrostatic lung oedema); inhaling high concentrations of smoke, toxins, or oxygen; severe burns; blood infections / sepsis; infection of the lung / pneumonia; aspirations, cerebral damage, or trauma to other parts of the body and lung transplantation. Lungs contain alveoli, which are tiny air sacs which pass the oxygen into the blood. During lung oedema, blood and fluid begin to leak into the alveoli. When this happens, alveoli can no longer pass oxygen into the blood. Because the lungs are inflamed and filled with fluid, the patient finds it increasingly difficult to breathe. The mortality rate of patients with pulmonary oedema in ALI/ARDS is 35% to 45% within two to four weeks. Currently, no specific drug treatment exists for patients suffering from pulmonary permeability oedema and patients having ARDS. ARDS is also a major economic burden to hospitals and health care budgets. It is estimated that due to a long ICU and hospital stay the cost of every saved live from ARDS is approximately \$70,000 USD.

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