PRESS RELEASE by APEPTICO

Vienna, Austria, March 3rd 2015

Vienna, Austria, 3rd March 2015: APEPTICO, a privately held biotechnology company developing peptide drugs, today announced that the phase IIa clinical study of AP301-peptide delivered top-line results in the treatment of primary graft dysfunction in patients following lung transplantation.

In lung transplantation (LuTX), a healthy lung from a deceased donor replaces the damaged lung of a patient to increase quality of life or even survival time of the recipient. Despite refinements in lung preservation and improvements in surgical techniques and perioperative care, primary graft dysfunction (PGD) remains a significant cause of early morbidity and mortality after lung transplantation. In addition to significant morbidity and mortality in the early postoperative period, PGD can also be associated with an increased risk of acute rejection that may lead to graft dysfunction in the long term. Currently, there is no effective pharmacotherapy available for treatment of PGD.

The proof-of-concept phase IIa clinical study was conducted at the Departments of Thoracic Surgery and Intensive Care Medicine of the Medical University of Vienna. The primary objective of this interventional, randomised, placebo-controlled study was to assess the clinical effect of orally inhaled AP301-peptide on treatment of PGD in patients after primary lung transplantation in comparison to placebo.

Results from this study showed that oral inhalation of AP301-peptide led to an early resolution of pulmonary oedema, pronounced improvement of gas exchange and normalisation of respiratory parameters, shortening of duration of mechanical ventilation and intensive care treatment, and earlier discharge of patients from hospital, when compared to placebo. On average, AP301-peptide treated patients were weaned from mechanical ventilation 1.5 days earlier, ICU treatment was terminated 3 days earlier and patients were discharged from the hospital up to 5 days earlier.

Dr. Bernhard Fischer, CEO of APEPTICO, stated: “We are very proud to have achieved this significant clinical goal. The results of this clinical study in lung transplantation strongly support previous findings from our previous trial in mechanically ventilated patients with pulmonary permeability oedema and ARDS. Our AP301-peptide is a very effective compound mediating recovery of normal lung function following lung injury and ischemia reperfusion injury. This major success would not have been possible without the enthusiastic support of the clinical study teams of Professor Walter Klepetko and Professor Clemens Aigner (Division Thoracic Surgery), and Professor Roman Ullrich and Professor Klaus Markstaller (Division of General Anaesthesia and Intensive Care Medicine) of the Medical University Vienna.” “Our excellent scientific and clinical data are the basis for partnership with global and specialised pharmaceutical and biotech companies” Dr. Fischer added.

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To Editors

About APEPTICO GmbH

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 APEPTICO's synthetic protein structures

APEPTICO's molecules are synthetically manufactured structural equivalents to domains of the human Tumour Necrosis Factor-α. The protein structures are water-soluble and can be administered into the lung by inhalation of liquid aerosol droplets of diameter 4 µm or less. Most recently, APEPTICO has successfully completed two phase II clinical trials with orally inhaled peptides for treatment of pulmonary permeability oedema and treatment of primary graft dysfunction following lung transplantation.

Currently, no specific drug treatment exists for life-threatening conditions such as pulmonary permeability oedema and ARDS, primary graft dysfunction following lung transplantation and high altitude pulmonary oedema.

APEPTICO's synthetic molecules have been granted orphan drug designations for various life-threatening pulmonary conditions by the European Medicines Agency (EMA) and by the Food and Drug Agency (FDA).

About lung transplantation and primary graft dysfunction

Approx. 5,000 lung transplantations are performed every year in Europe and North America according to the International Registry for Heart and Lung Transplantations. Lung transplantation is considered a rare event and affects mainly patients with severe COPD/emphysema, idiopathic pulmonary fibrosis, cystic fibrosis, alpha-1 deficiency, idiopathic pulmonary arterial hypertension, bronchiectasis, connective tissue disease and obliterative bronchiolitis.

Primary graft dysfunction occurs in approx. 20% of lung transplant recipients within the first 72 hours. PGD is characterized by poor oxygenation as the main criterion for the condition, and is also characterized by low pulmonary compliance, interstitial/alveolar oedema, pulmonary infiltrates on chest radiographs, increased pulmonary vascular resistance, intrapulmonary shunt and acute alveolar injury. With 28% primary graft dysfunction is the main cause of death in the first 30 days following lung transplantation.

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