PRESS RELEASE

The Committee for Orphan Medicinal Products of the European Medicines Agency grants orphan drug designation to APEPTICO's development compound AP301 for treatment of primary graft dysfunction following lung transplantation

5th October 2015, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing novel peptide-based drugs, today announced that its development compound AP301 has been granted orphan drug designation by the Committee for Orphan Medicinal Products of the European Medicines Agency for the orphan indication 'treatment of primary graft dysfunction following lung transplantation'.

Primary graft dysfunction (PGD) refers to acute allograft dysfunction within the first 72 h following lung transplantation in the absence of identifiable secondary causes. PGD is characterized by poor oxygenation and low pulmonary compliance; it affects approx. 30% of all lung transplant recipients for whom it represents a significant cause of early morbidity and mortality. Currently, no satisfactory method of treatment exists.

This was the first time that a development compound has been granted orphan medicinal product designation for this life-threatening condition by the European Medicines Agency. APEPTICO's request was based on results from numerous non-clinical studies and excellent results from a phase II clinical trial in lung transplant patients. The majority of non-clinical data have been generated during scientific collaborations of APEPTICO with Professor Rudolf Lucas from the Medical College of Georgia (Georgia Regents University, Augusta, USA) and with Professor Rosa Lemmens-Gruber's team from the Department of Pharmacology & Toxicology of the University Vienna (Vienna, Austria). The phase II "Pilot study to investigate the clinical effect of orally inhaled AP301 on treatment of primary graft dysfunction in mechanically ventilated patients after primary lung transplantation" was conducted by Professor Walter Klepetko's lung transplant team from the Department of Thoracic Surgery of the Medical University Vienna (Vienna, Austria).

Dr. Bernhard Fischer, CEO of APEPTICO commented: "I am very pleased that the European Medicines Agency has approved our application for orphan drug designation for AP301 for treatment of primary graft dysfunction following lung transplantation. Until today there exists no approved therapy for this life-threatening condition." Dr. Fischer added, "We are very proud that Professor Clemens Aigner from the Department of Thoracic Surgery was allowed by the scientific steering committee to present the late breaking clinical data at this year's International Congress of the European Respiratory Society (October 26th 2015, Amsterdam, Netherlands)."

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Notes to Editors:

About APEPTICO Forschung und Entwicklung 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 therapeutic protein structures

APEPTICO's proprietary therapeutic molecules are synthetically manufactured structural equivalents to domains of the human proteins. Liquid and dry powder formulations of such protein structures can be administered into the lung by inhalation of aerosol particles with diameter 5 micrometres or less. Most recently, APEPTICO has successfully completed two Phase II clinical trials with orally inhaled peptides for treatment of patients with pulmonary permeability oedema and ARDS (acute respiratory distress syndrome) and for treatment of patients with primary graft dysfunction following lung transplantation. Currently, no specific drug treatments exist for both acute and life-threatening pulmonary dysfunctions.

About primary graft dysfunction (PGD)

PGD after lung transplantation represents a multifactorial parenchymal injury and dysfunction to the transplanted lung that develops in the first 72 hours after transplantation in the absence of identifiable secondary causes.

The most common indications for lung transplantation are chronic obstructive pulmonary disease (COPD) including emphysema, idiopathic pulmonary fibrosis and cystic fibrosis. Other indications include alpha1-anti-trypsin deficiency emphysema, idiopathic pulmonary arterial hypertension, and sarcoidosis.

PGD is characterized by poor oxygenation and low pulmonary compliance as the main criterion for the condition, formation of interstitial & alveolar oedema, pulmonary infiltrates on chest radiographs, increased pulmonary vascular resistance, intrapulmonary shunt and acute alveolar injury, as revealed by diffuse alveolar damage (IDAD) on pathology. PGD occurs in approx. 30% of lung transplant recipients and it represents a significant cause of early morbidity and mortality to lung transplant patients.

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