PRESS RELEASE by APEPTICO

Vienna, Austria, December 1st 2014

Vienna, Austria, 1st December 2014: APEPTICO, a privately-held biotechnology company developing peptide drugs, today announced that it will present major scientific break-through results for its AP301-peptide based inhalation medicine at leading international conferences in December this year.

Scientists of APEPTICO, in close collaboration with the Department of Pharmacology and Toxicology of the University Vienna, have discovered essential details of the molecular interactions of APEPTICO's AP301-peptide drug compound and its pulmonary tissue target, the amiloride-sensitive epithelial sodium ion channel (ENaC). APEPTICO's AP301-peptide, also known as the 'lectin-like domain', is highly specific for its binding to glycan structures. Based on site-directed mutagenesis of ENaC subunits, individual glycosylation sites of an outer-loop structure of ENaC were removed by mutations, followed by heterologous expression of mutated ENaC in HEK-293 cells and electrophysiological analysis of sodium-ion movement through mutated ion channels. The 'glycosylation-dependent activation of ENaC by AP301-peptide' will be presented during the European Peptide Society conference in Salzburg (4th December 2014).

Since 2009 APEPTICO has successfully developed the AP301-peptide inhalation medicine for treatment of pulmonary permeability oedema and for treatment of primary graft dysfunction of the lung of mechanically ventilated patients. Since it was founded, APEPTICO has become a champion in pulmonary delivery of biologic macromolecules to patients with life-threatening lung diseases. In recognition of this major achievement, APEPTICO has been invited to present the AP301-peptide drug development story at this years' annual conference 'Drug Delivery to the Lung' of The Aerosol Society held in Edinburgh from 10th to 12th December 2014.

Bernhard Fischer, CEO of APEPTICO commented: "I am very proud that our research consortium has further elucidated at molecular level the interaction between the AP301-peptide drug and the pulmonary ENaC receptor, that brings about alveolar liquid clearance in patients with lung oedema." "Having been selected to present the AP301 story at this year's 'Drug Delivery to the Lung' international conference, marks a highlight in our efforts to develop better therapeutic treatment option for intensive care patients" he added.

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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 AP301-peptide / TIP-peptide

The AP301-peptide (synonym to TNF-derived TIP-peptide) is a synthetic molecule whose structure bases on the lectin-like domain of the human Tumour Necrosis Factor α. The AP301 peptide is water-soluble and can be administered into the lung by oral inhalation. Formulated AP301 is easily nebulised and the resulting aerosol is composed of peptide/water droplets of diameter 4 µm or less. APEPTICO's most recent clinical phase II proof-of-concept study (ClinicalTrials.gov ID NCT01627613) demonstrated that orally inhaled AP301-peptide activates alveolar liquid clearance in mechanically ventilated patients with pulmonary permeability oedema and ARDS.

Comprehensive research and development studies conducted by the APEPTICO research consortium demonstrated that AP301-peptides are effective therapeutic molecules in various forms of pulmonary oedema, such as pulmonary permeability and hydrostatic oedema, high altitude pulmonary oedema (HAPE), pulmonary oedema associated with acute lung injury (ALI) and acute respiratory distress syndrome (ARDS), pulmonary oedema resulting from pneumonia and sepsis, and primary graft dysfunction following lung transplantation.

APEPTICO's AP301 has been granted orphan drug status (i) for treatment of pulmonary permeability oedema in ALI/ARDS, (iii) for treatment of primary graft dysfunction following lung, and (iii) for treatment of high altitude pulmonary oedema by the European Commission and European Medicines Agency (EMA) and 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 where the oxygen is passed into the blood. During lung oedema, blood and fluid begin to leak into the alveoli. When this happens, oxygen cannot enter the alveoli, which means oxygen no longer passes 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 ARDS, patients developing primary graft dysfunction following lung transplantation and patients having acute high altitude pulmonary oedema.

Contact

Univ.-Doz. Dr. Bernhard Fischer, Chief Executive Officer
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