

PRESS RELEASE

APEPTICO initiates phase II clinical trial with AP301 in patients with primary graft dysfunction following lung transplantation

Vienna, Austria, April 17, 2013 - APEPTICO, a privately-held biotechnology company developing peptide drugs based on its PEPBASE™ discovery technology, today announced that the Ethics Committee of the Medical University of Vienna has approved the company's application to perform a phase IIa clinical study in male and female patients following lung transplantation to investigate the clinical effect of repetitive orally inhaled doses of AP301 on primary graft dysfunction.

AP301 is synthetic peptide which has been shown in animal studies in rats and pigs following application by inhalation of the nebulised compound, to prevent and treat ischemia reperfusion injury, to significantly improve gas exchange in pre-damaged donor lungs and to activate lung oedema reabsorption. Until today, no medicinal product has been specifically authorized by medicines agencies for prevention and treatment of primary graft dysfunction / ischemia reperfusion injury in the lung following lung transplantation.

The interventional, randomized, placebo-controlled, parallel-group study entitled "Pilot study to investigate the clinical effect of orally inhaled AP301 on treatment of primary graft dysfunction (PGD) in mechanically ventilated patients after primary lung transplantation" will be conducted at the Vienna General Hospital and the Medical University of Vienna, Austria. Immediately after lung transplantation, patients will be screened for early signs of primary graft dysfunction. Patients who are included into the study will receive doses of AP301 or matching placebo converted into an aerosol by state-of-the-art nebuliser technology over a period up to 7 days.

"We are very pleased that the Ethics Committee has approved our study" said Bernhard Fischer, CEO of APEPTICO. "Prevention and treatment of primary graft dysfunction represents an unmet medical need as no specific therapy or medicinal product has been approved so far for this life-threatening condition. Having successfully completed our Phase I clinical trial in 2011, this is our second Phase II clinical study in pulmonary patients. We initiated a Phase II clinical study in patients suffering from oedematous respiratory failure (ALI/ARDS) in summer 2012 and the new clinical study in lung transplantation patients broadens the therapeutic application of our lead compound AP301."

Notes to Editors:

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™ and PEPSCREEN™ to significantly reduce cost and to shorten time to market.

About AP301 peptide family

AP301 and derived peptides are synthetic peptide molecules whose structures are based on naturally occurring motifs. AP301 peptides are 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. AP301 and derived peptides are designed for activation of the pulmonary epithelial sodium channel (ENaC). Activation of ENaC by AP301 results in accelerated lung oedema clearance in the airspace. Comprehensive research and development conducted by APEPTICO has demonstrated that AP301 peptides are effective in animal models of various forms of pulmonary oedema, including high altitude pulmonary oedema, acute lung injury / acute respiratory distress syndrome, pneumonia, influenza virus lung infection, and lung transplantation. Currently, AP301 is subject to a Phase IIa clinical study for the treatment of patients suffering from life-threatening oedematous respiratory failure.

About Primary Graft Dysfunction

Primary Graft Dysfunction (PGD) / Ischemia Reperfusion Injury (IRI) 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, as revealed by diffuse alveolar damage (DAD) on pathology. PGD occurs in approximately 20% of lung transplant recipients and patients face prolonged ventilation, prolonged stays in the ICU and the hospital overall, increased medical costs, and increased risk of morbidity and mortality.

Contact

Univ.- Doz. Dr. Bernhard Fischer, Chief Executive Officer
APEPTICO Forschung und Entwicklung GmbH
Mariahilferstraße 136, Top 1.15, A-1150 Vienna, Austria
Mail: b.fischer@apeptico.com
URL: www.apeptico.com