

PRESS RELEASE

APEPTICO's lead molecule AP301 has been validated in an experimental lung transplantation model

23rd February, 2010, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing novel peptide-based drugs, today announced that its lead molecule AP301 has been validated in an experimental lung transplantation model where intratracheal application of AP301 dramatically improved oxygenation after lung transplantation.

APEPTICO's AP301 is a 17-amino acid cyclic peptide representing the "TIP-motif" of the human cytokine tumour necrosis factor. The international leading journal Critical Care Medicine has published in its latest issue (No. 38(3), pp.871-878) the article "The lectin-like domain of tumor necrosis factor improves lung function after rat lung transplantation - potential role for a reduction in reactive oxygen species generation" by Dr. Jürg Hamacher et al. This study was a collaboration between Prof. Dr. Rudolf Lucas from the Medical College of Georgia, the inventor of the TIP peptide and the University Hospital Bern, Switzerland. The results from this study, featured in the Editorial of the same issue, demonstrate that in a left lung transplantation model in rats, accompanied by ischemia reperfusion injury, endothelial hyperpermeability and Permeability Oedema which ensuing dramatically reduced oxygenation, APEPTICO's AP301 dramatically improves oxygenation (assessed by the $\text{PaO}_2/\text{FIO}_2$ ratio) 24 h after lung transplantation. AP301 accomplishes this by significantly decreasing the production of reactive oxygen species and by reducing neutrophil sequestration in the lung, thus mitigating the secondary effects of reoxygenation and reperfusion.

Dr. Bernhard Fischer, CEO of APEPTICO commented: "We are very happy about these results and that this extraordinary study was high lighted by an Editorial Comment in the Critical Care Medicine journal with the words »the study takes us a step closer in developing therapeutic measures to combat Acute Lung Injury and various forms of Adult Respiratory Distress Syndrome«. (Critical Care Medicine (2010), 38(3), 997-998).

Prof. Dr. Rudolf Lucas, CSO of APEPTICO added: "These studies clearly demonstrate a therapeutic potential of the AP301 compound and will pave the way towards testing the compound also in more chronic models of lung transplantation as well as in other organ models of ischemia-reperfusion damage".

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Notes 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 any risk of transmitting microbial and viral infections. Development cost and time to market are significantly reduced if compared to the recombinant development process of biomolecules. APEPTICO's development platform PEPBASE™ combines structural, functional and clinical data from relevant biopharmaceuticals and well-characterised proteins. Based on preclinical and clinical data, including adverse reactions, risk factors and contraindications to be circumvented and supported by structural, biochemical and physicochemical data, for each relevant protein a specific profile is established that links biological & functional properties with discrete structural elements.

About Lung Transplantation and Primary Graft Dysfunction

Primary Graft Dysfunction (PGD), a clinical variant of Acute Lung Injury (ALI), is an important complication of lung transplantation in the immediate postoperative period. Based on the recommendations of the International Society for Heart and Lung Transplantation, PGD is currently graded based on PaO₂/ FIO₂ ratio and chest infiltrates evaluated at various time points up to 72 hrs after transplantation. PGD occurs in approximately 10% to 25% of recipients and is the leading cause of morbidity and death in the early posttransplant period. Furthermore, PGD has important long-term consequences decreasing performance status and increasing the risk of bronchiolitis obliterans syndrome. Increased pulmonary alveolar capillary permeability associated with impaired clearing of alveolar fluid is the ultimate pathophysiological mechanism contributing to PGD, as in many other types of ALI and Adult Respiratory Distress Syndrome

About AP301

AP301 is a synthetic peptide that corresponds to a structural motif of the human Tumour Necrosis Factor alpha. It is water soluble and can be administered into the lung by instillation or by inhalation. Formulated AP301 can be nebulised and the resulting aerosol is composed of peptide/water droplets of sizes of 4 µm or less. AP301 has been designed originally for the treatment of Acute Lung Injury and Acute Respiratory Distress Syndrome. Additional research demonstrated that AP301 has additional significant potential in related clinical indications, such as prevention and treatment of pulmonary permeability oedema, prevention of progression of acute hypoxemic respiratory failure due to bacterial/viral pneumonia and prevention of ischemia reperfusion injury. AP301 activates lung oedema reabsorption and protects both endothelial and epithelial lung cells from virulence factor- and reactive oxygen species-induced hyper-permeability of lung capillaries.

AP301 has received Orphan Drug Designation by the EMEA (European Community) for the treatment of Acute Lung Injury and by the FDA (USA) for the prevention of ischemia reperfusion injury in the lung during lung transplantation".

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