PRESS RELEASE

APEPTICO granted Orphan Drug Designation by FDA for development compound AP301

10th February, 2010, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing novel peptide-based drugs, today announced that it has received Orphan Dug Designation in the USA from the Food and Drug Administration (FDA) for APEPTICO's development compound AP301. AP301 has been granted Orphan Drug Designation in the USA for "prevention of ischemia reperfusion injury in the lung during lung transplantation".

APEPTICO's AP301 is a 17 amino acids cyclic peptide. It represents "TIP-motif" of the human tumour necrosis factor alpha. Upon pulmonary application the AP301 peptide exerts a favourable effect on lung function and decreased alveolar infiltration in the setting of ischemia reperfusion injury associated with lung transplantation. Intratracheally administered AP301 peptide leads to a major improvement of gas exchange and a diminished neutrophil count in the bronchoalveolar fluid.

Dr. Bernhard Fischer, CEO of APEPTICO commented: "I am pleased that the FDA has approved the Orphan Drug Designation for AP301 for the prevention of ischemia reperfusion injury in the lung during lung transplantation. This encouraging step builds on the announcement by the EMEA in July 2009 of granting of Orphan Medicinal Product Designation for AP301 in the EU for "treatment of acute lung injury". There remains a real unmet medical need for innovative products that work to prevent ischemia reperfusion injury that is very frequent experienced following solid organ transplants. There are no products currently authorized in the US to prevent ischemia reperfusion injury during lung transplantation. With our innovation we hope to make an important contribution to the field of clinical medicine and to significantly improve patient outcomes in lung transplantation".

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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.

Ischemia Reperfusion Injury

Restoration of blood supply to an organ after a critical period of ischemia results in parenchymal injury and dysfunction of the organ referred to as reperfusion injury. Ischemia reperfusion injury is often seen in organ

transplants, major organ resections and in shock. Despite refinements in lung preservation and improvements in surgical techniques and perioperative care, ischemia reperfusion-induced lung injury remains a significant cause of early morbidity and mortality after lung transplantation. The most common indications for lung transplantation are chronic obstructive pulmonary disease (COPD) including emphysema, idiopathic pulmonary fibrosis and cystic fibrosis. Ischemia reperfusion injury is the end result of multiple pathologic mechanisms. It 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 on pathology. Clinically, patients face prolonged ventilation, prolonged stays in intensive care in the hospital, increased medical costs, and increased risk of morbidity and mortality.

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.

About Orphan Drugs in the US

An orphan drug is a pharmaceutical agent that specifically treats a rare medical condition, the condition itself being referred to as an orphan disease. The US Orphan Drug Act is meant to encourage pharmaceutical companies to develop drugs for rare diseases. Under the law, companies that develop such a drug for a disorder affecting fewer than 200,000 people in the United States may sell it without competition for seven years and may get clinical trial tax incentives.

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