PRESS RELEASE

APEPTICO granted Orphan Medicinal Product Designation by EMEA for lead product AP301

20th July, 2009, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing novel peptide-based drugs, today announced that it has received Orphan Medicinal Product Designation in the European Union from the European Medicines Agency (EMEA) for APEPTICO's lead product AP301 ("Human tumour necrosis factor alpha-derived peptide") for the "treatment of Acute Lung Injury".

AP301 is APEPTICO's lead product and is a peptide version of the "TIP-motif" of the human tumour necrosis factor alpha which acts as a potent and target-specific peptide activating alveolar liquid reabsorption and counter-acts hyper-permeability of both endothelial and epithelial lung cells. Alveolar oedema and hyper-permeability are main causes of Acute Lung Injury.

Dr. Bernhard Fischer, CEO of APEPTICO commented: "I am pleased that the EMEA has approved the Orphan Medicinal Product Designation for AP301 for treatment of Acute Lung Injury and that the focus of the EMEA is on medicinal product quality. There is a real unmet medical need for a product that works to clear excess of alveolar liquid and that counter-acts both microbial toxins and reactive oxygen species which lead to lung microvascular damage. Currently there is no specific therapy authorised in Europe to prevent or treat this condition and we hope to make an important contribution to the field of clinical medicine and to improve patient outcomes in Acute Lung Injury."

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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 PEPBASETM 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 Acute Lung Injury and Acute Respiratory Distress Syndrome

Acute Lung Injury (ALI) is a pulmonary disorder characterised by acute onset, bilateral pulmonary infiltrates on chest radiograph consistent with pulmonary oedema, poor systemic oxygenation, and the absence of evidence of left arterial hypertension. There are many possible causes of ALI, such as inhaling high concentrations of smoke, toxins, or oxygen; severe burns; blood infections; lung infections; or trauma to other parts of the body. Acute Respiratory Distress Syndrome (ARDS) is the most catastrophic form of ALI.

Lungs contain alveoli, which are tiny air sacs where the oxygen is passed into the blood. In ALI blood and fluid begin to leak into the alveoli. When this happens, oxygen cannot enter the alveoli, which means oxygen is no longer getting into the blood. Because the lungs are inflamed and filled with fluid, the patient finds it increasingly difficult to breathe. ALI is life-threatening because it makes breathing extremely difficult. The mortality rate of ALI/ARDS is 30% to 60% within 2 to 4 weeks.

Currently, no approved pharmacological therapy for ALI is available. ALI patients are treated with intensive support, which includes various strategies for assisted ventilation. A large number of treatments have failed to improve survival. These include glucocorticosteroids, surfactant, prostaglandin E1, ketoconazole, prostacyclin, nitric oxide, and almitrine.

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 as aerosol. AP301 has been designed for the treatment of Acute Lung Injury and Acute Respiratory Distress Syndrome and has additional significant potential in other forms of permeability oedema and ischemia-reperfusion injury, such as lung transplantation and pneumonia. AP301 activates lung oedema reabsorption and protects both endothelial and epithelial lung cells from microbial toxin- and reactive oxygen species-induced hyper-permeability.

About Orphan Medicinal Product Designation in the EU

“Orphan medicinal products” are intended for the diagnosis, prevention or treatment of rare and life-threatening or chronically debilitating conditions. The legislative framework for orphan medicines aims to stimulate research and development of medicines for rare diseases by providing incentives to the pharmaceutical industry. These incentives include fee reductions or exemptions for regulatory services, 10 year marketing exclusivity and direct access to EU registration via a centralized procedure, resulting in one single license for 27 EU member states.

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