

PRESS RELEASE

APEPTICO Initiates Phase I Trial with AP301 in Pulmonary Oedema

Vienna, Austria, April 07, 2011 - APEPTICO, a privately-held biotechnology company developing peptide drugs based on its PEPBASE™ discovery technology, today announced the initiation of a Phase I clinical trial with its lead product AP301 to assess the safety and tolerability of the orally inhaled peptide drug. AP301 is being developed for the treatment of oedematous respiratory failure in patients suffering from lung infection, lung injury and lung transplantation.

AP301 is the first compound against respiratory failure caused by pulmonary oedema that activates lung oedema reabsorption and thus differs from the currently used anti-inflammatory treatment that often fails in patients with acute lung injury. The synthetic peptide AP301 activates alveolar liquid clearance (ALC) and prevents both endothelial and epithelial lung tissue from hyper-permeability as a result of microbial and viral lung infections. AP301 also prevents ischemia reperfusion injury following lung transplantation in the lower respiratory tract.

The randomized, double-blind, placebo-controlled, dose escalating study is enrolled in Austria. Up to 48 patients will receive a single dose of AP301 or matching placebo converted into an aerosol by state-of-the-art nebuliser technology.

"We are very pleased to expand the development of our lead molecule AP301 into clinical studies, particularly as we have faced widespread scepticism regarding the usefulness of peptide drugs in inhalation therapy," said Bernhard Fischer, CEO of APEPTICO. "Treatment of oedematous respiratory failure represents an unmet medical need as no specific therapy or medicinal product has been approved so far for the prevention and treatment pulmonary oedema caused by hyper-permeability."

APEPTICO seeks partner in Influenza

"Pulmonary oedema is the primary cause of death in patients with influenza. Due to our promising results with AP301 in mice infected with influenza virus and a porcine model of acute lung injury, we are very confident that we will soon find partners in the pharmaceutical industry for further development of AP301," said Bernhard Fischer.

Treatment of influenza virus-infected mice with AP301 results in a significant reduction of oedema fluid accumulation in the air space and increased ALC. AP301 acts synergistically with anti-viral neuraminidase inhibitor, such as oseltamivir and zanamivir, in influenza virus-infected mice by reducing virus-mediated lung oedema and by prevention of endothelial/epithelial hyper-permeability. In a porcine model of acute lung injury, inhalation of AP301 peptide results in a sustained improvement of the lung function according to the parameters oxygenation index, extravascular lung water (EVLWI) and pulmonary shunt fraction.

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 oral inhalation. Formulated AP301 can be nebulised and the resulting aerosol is composed of peptide/water droplets of diameter 3 µm or less. AP301 was originally designed 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 EMA (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.

About APEPTICO GmbH - www.apeptico.com

APEPTICO, a privately-held biotechnology company located in Austria, develops peptide-based products targeting chronic and life-threatening diseases using its PEPBASE™ discovery technology.

PEPBASE™ combines structural, functional and clinical data of relevant biopharmaceuticals and well-characterised proteins to establish a specific profile for each protein that links biological & functional properties with discrete structural elements. Accordingly, APEPTICO's synthetic peptides correspond to validated, pharmacodynamic active structures and domains of proteins and biopharmaceuticals. By focusing on synthetically produced protein structures APEPTICO avoids any risk of transmitting microbial and viral infections. Development cost and time to market are significantly reduced compared to the recombinant development process of biomolecules.

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