

PRESS RELEASE

APEPTICO Announces Successful Completion of Phase I Trial with AP301 in Oedematous Respiratory Failure

Vienna, Austria, 25th October, 2011- [APEPTICO GmbH](#), a biotechnology company developing peptide drugs based on its PEPBASE™ discovery technology, today announced completion of a Phase I clinical trial for its pulmonary sodium ion channel activator AP301. The orally inhaled drug candidate was safe and well-tolerated by all study participants. AP301 is being developed for the prevention and treatment of oedematous respiratory failure in patients suffering from lung infection, lung injury and lung transplantation.

The Phase I single-center clinical trial evaluated the safety, tolerability and pharmacokinetic profile of AP301 in an orally inhaled, double-blind, randomized, placebo-controlled, dose escalation study in 48 healthy male volunteers. AP301 was shown to be safe at all doses investigated, with no reports of serious adverse side effects.

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 ischaemia reperfusion injury following lung transplantation in the lower respiratory tract.

"The successful completion of our Phase I trial is an important step for APEPTICO's drug development program" said Dr. Bernhard Fischer, CEO of APEPTICO. "We look forward to starting the Phase IIa trial with the aerosol formulation of AP301 in 2012, and are committed to building on our success with peptide drugs."

About AP301

AP301 is a fully synthetic peptide molecule whose structure is based on the lectin-like domain of human Tumour Necrosis Factor alpha. The AP301 peptide is water soluble and can be administered into the lung by oral inhalation. AP301 is designed to activate the pulmonary epithelial sodium channel (ENaC) which results in an accelerated oedema clearance in the airspace. Comprehensive research and development conducted by APEPTICO has demonstrated that the AP301 peptide is effective to clear lung water in animal models of pulmonary permeability oedema, pneumonia, influenza virus lung infection, acute lung injury and lung transplantation. AP301 has received Orphan Drug Designation by the EMA and by the FDA for various indications.

About oedematous respiratory failure

Respiratory failure occurs when the respiratory system fails in oxygenation and/or carbon dioxide elimination. Oedematous respiratory failure is caused by a massive and life-threatening pulmonary oedema. Pulmonary oedema occurs when fluid leaks from the pulmonary capillary network into the lung interstitium and alveoli. When this happens, oxygen cannot enter the alveoli, which means oxygen no longer passes into the blood. There are many possible causes of lung oedema, 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 lung injury (ALI) and acute respiratory distress syndrome (ARDS) are catastrophic forms of lung oedema. The mortality rate of patients

with pulmonary oedema in ALI/ARDS is 30% to 60% within 2 to 4 weeks. Currently, no specific drug treatment exists for patients suffering from hyper-permeability-caused lung oedema.

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.

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