

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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PRESS RELEASE

The 2011 Annual Conference of the European Respiratory Society has been a major success for APEPTICO Forschung und Entwicklung GmbH

29th September, 2011, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing novel peptide-based drugs for the treatment of life threatening lung diseases today announced that the 2011 Annual Conference of the European Respiratory Society has been a major success for the company.

At the 2011 Annual Congress of the European Respiratory Society (ERS) in Amsterdam (The Netherlands, September 24th to 28th 2011), APEPTICO has presented significant research results of its clinical stage development compound AP301. The beneficial effects of APEPTICO's development compound AP301, also known as "TIP-peptide", have been subject of three presentations at this prestigious congress.

Professor Dr. Rudolf Lucas (Georgia Health Sciences University, Augusta, USA) reported that the AP301 TIP-peptide reduces lung dysfunction in experimental influenza A virus infection *in vitro* and *in vivo*. Dr. Susan Tzotzos reported on characterisation of TNF-alpha lectin-like domain derived AP301 TIP-peptides associated with improved alveolar fluid clearance in pulmonary oedema. The potential synergism of AP301 and anti-viral drugs, such as oseltamivir and zanamivir, was reported in by Dr. Hendrik Fischer.

The AP301 peptide is being developed by APEPTICO for inhalation therapy for prevention and treatment of Oedematous Respiratory Failure. AP301 activates the pulmonary epithelial sodium ion channel (ENaC) and prevents Protein Kinase C activation in lung tissues. It thus accelerates pulmonary oedema reabsorption and stabilises endothelial-epithelial barrier function in life-threatening conditions resulting from hyper-permeability of lung micro-capillaries. Currently, AP301 is subject to a Phase I clinical study in the Vienna General Hospital.

Extracts from presentations

Prof. Dr. R. Lucas: "The AP301 "TIP-peptide" which reduces PLY-induced oedema, can blunt influenza A virus (IAV) induced Alveolar Liquid Clearance dysfunction and combined IAV/PLY-induced barrier dysfunction. The TIP peptide represents a therapeutic candidate for the treatment of IAV-associated lung dysfunction, since it interferes with both IAV infection-associated ALC and barrier dysfunction, upon reducing PKC- α activation."

Dr. S. Tzotzos: "Our data suggest that TIP-peptides with charge distribution and interatomic distances most closely resembling the 3D structure of the native lectin-like domain of TNF-alpha, are those with greater ability to enhance activation of sodium current through ENaC. No standard therapy exists for pulmonary oedema, thus these TIP-peptides represent promising therapeutic agents for activating sodium uptake from the alveolar fluid through ENaC and improving clinical outcome in this condition."

Dr. H. Fischer: "Influenza A is a serious public health problem that causes severe illnesses and deaths for higher risk populations. Antiviral drugs like oseltamivir and zanamivir block increase and spreading of the virus in the body, however already existing virus particles will not be affected. 2/3 of patients show pulmonary oedema that can deteriorate to ALI/ARDS. Current experiments suggest a benefit of combining anti-viral drugs (neuraminidase inhibitors) and AP301 a substance with alveolar liquid clearing activity."

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Notes to Editors:

About APEPTICO GmbH

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About the AP301 peptide family

AP301 and derived peptides are synthetic molecules whose structures are based on the lectin-like domain of human Tumour Necrosis Factor alpha. AP301 peptides are water soluble and can be administered into the lung by oral inhalation. Formulated AP301 is easily nebulised and the resulting aerosol is composed of peptide/water droplets of diameter 4 µm or less. AP301 and derived peptides are designed for activation of the pulmonary epithelial sodium channel (ENaC). Activation of ENaC by AP301 peptides results an accelerated oedema clearance in the airspace. Comprehensive research and development conducted by APEPTICO has demonstrated that AP301 peptides are effective in animal models of pulmonary permeability oedema, pneumonia, influenza virus lung infection, Acute Lung Injury / Acute Respiratory Distress Syndrome and lung transplantation. AP301 has received Orphan Drug Designation by the EMA and by the FDA for various indications.

Currently, AP301 is subject to a Phase I clinical study in the General Hospital in Vienna.

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. 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.

Lungs contain alveoli, which are tiny air sacs where the oxygen is passed into the blood. During lung oedema, blood and fluid begin to leak into the alveoli. When this happens, oxygen cannot enter the alveoli, which means oxygen no longer passes into the blood. Because the lungs are inflamed and filled with fluid, the patient finds it increasingly difficult to breathe. 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 ERS Conference

The ERS Conference is the largest international conference specialising in pulmonary medicine. It provides a unique forum where scientists and medical professionals from around the world have the opportunity to meet and exchange ideas and information in the field of respiratory medicine. The scientific programme of the ERS Congress aims to provide a perfect balance between clinical education and the latest scientific developments. The ERS Congress highlights key issues in the diagnosis, management and treatment of respiratory diseases, giving clinicians and research scientists the opportunity to report the latest findings in basic, clinical and population research.

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PRESS RELEASE

APEPTICO presents significant research results of its inhalation therapy for prevention and treatment of Oedematous Respiratory Failure at the 2011 Annual Congress of the European Respiratory Society

09th September, 2011, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing novel peptide-based drugs for the treatment of life threatening lung diseases today announced that it will present significant research results of its inhalation therapy for prevention and treatment of Oedematous Respiratory Failure at the 2011 Annual Congress of the European Respiratory Society.

At the 2011 Annual Congress of the European Respiratory Society (ERS) in Amsterdam (The Netherlands, September 24th to 28th 2011), APEPTICO will present significant research results of its inhalation therapy for prevention and treatment of Oedematous Respiratory Failure to the scientific community. The scientific advisory board of the ERS has appointed in total three contributions of APEPTICO to be presented at this major event. In the oral presentation entitled “Characterisation of TNF-alpha lectin-like domain derived peptides associated with improved alveolar fluid clearance in pulmonary oedema” APEPTICO’s strategy for design and pharmacodynamic assessment of state-of-the-art lung ENaC agonists will be presented. Professor Dr. Rudolf Lucas will give a talk entitled “The lectin-like domain of TNF reduces lung dysfunction in experimental Influenza A virus infection” and researchers of APEPTICO will present additional scientific findings in “Potential synergism of drugs with anti-viral and pulmonary oedema clearance activity may be advantageous for influenza patients”.

APEPTICO develops synthetic peptide drugs, based on the structural motif of the lectin-like domain of human tumour necrosis factor alpha (TNF-alpha), which activate the pulmonary epithelial sodium ion channel (ENaC) and thus accelerate pulmonary oedema reabsorption in life-threatening conditions such as pneumonia, influenza virus lung infection and Acute Lung Injury / Acute Respiratory Distress Syndrome.

APEPTICO’s lead peptide AP301 is currently subject to a Phase I clinical study in the Vienna General Hospital.

The ERS Congress is the largest international conference specialising in pulmonary medicine. It provides a unique forum where scientists and medical professionals from around the world have the opportunity to meet and exchange ideas and information in the field of respiratory medicine. The scientific programme of the ERS Congress aims to provide a perfect balance between clinical education and the latest scientific developments. The ERS Congress highlights key issues in the diagnosis, management and treatment of respiratory diseases, giving clinicians and research scientists the opportunity to report the latest findings in basic, clinical and population research.

Dr. Bernhard Fischer, CEO of APEPTICO commented: “I am pleased that the scientific organising committee of the ERS Annual Congress is giving us the opportunity to present the progress of our drug development programme - the development of new medicines for prevention and treatment of Oedematous Respiratory Failure. Today no specific drug treatment exists for patients suffering from hyper-permeability-caused lung oedema.”

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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. 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.

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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 ischaemia 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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