PRESS RELEASE

APEPTICO publishes significant scientific results of its development compound AP301

Vienna, Austria, December 3rd, 2013: APEPTICO, a privately-held biotechnology company developing peptide drugs, today announced that significant scientific results of its development compound AP301 have been published in *Molecular Pharmacology* and *The Journal of Clinical Pharmacology*, summarising the mode of action of AP301 in activating the amiloride-sensitive epithelial sodium ion channel (ENaC) and presenting the results of APEPTICO's *first-in-man* clinical study of orally inhaled AP301.

APEPTICO develops the AP301 peptide compound for the activation of pulmonary oedema clearance in intensive care patients with life-threatening oedematous respiratory failure and acute respiratory distress syndrome.

The December volume of *Molecular Pharmacology* publishes the original research article "Mechanism of action of novel lung edema therapeutic AP301 by activation of the epithelial sodium channel" (http://molpharm.aspetjournals.org/content/84/6/899.abstract) resulting from APEPTICO's scientific collaboration with the Department of Pharmacology and Toxicology of the University of Vienna. The mode of action of AP301 peptide in activating the amiloride-sensitive epithelial sodium ion channel (ENaC) was studied in A549 lung epithelial cells as well as in human embryonic kidney cells and chinese hamster ovary cells heterologously expressing human ENaC subunits α, β, γ, and δ. The data suggest that AP301 specifically targets endogenously and heterologously expressed ENaC, activates proteolytically processed ENaC in a reversible manner, requires the pore-forming α- or δ-subunit co-expressed with βγ-subunits for maximal activity, and requires glycosylated extracellular domains of ENaC to enable binding of AP301 to the ion channel.

In collaboration with the Department of Clinical Pharmacology of the Medical University of Vienna, safety and tolerability of orally inhaled AP301 peptide was assessed in a FIM (first-in-man) clinical study at the Vienna General Hospital. The results of this study are summarised as "A FIM study to assess safety and exposure of inhaled single-doses of AP301–A specific ENaC channel activator for the treatment of acute lung injury" in the December volume of *The Journal of Clinical Pharmacology* (http://onlinelibrary.wiley.com/doi/10.1002/jcph.203/abstract). In the phase I clinical study 48 subjects received treatment, and completed the study as per protocol. No serious or local adverse events were noted. None of the assessments indicated notable dose or time-related alterations of safety outcomes. Inhaled AP301 single doses up to 120 mg were safe and well tolerated by study subjects. Distribution of inhaled AP301 was largely confined to the lung, as indicated by very low AP301 systemic exposure levels.

Dr. Bernhard Fischer, CEO of APEPTICO, commented: "2013 was another very productive year in the research & development programme of APEPTICO, illustrating that the Company's strategy of investigating the mode of action and clinical use of its lead compound AP301 through a network of research collaborations, is paying off." "AP301 has successfully completed a phase I clinical study and is currently undergoing two different phase II clinical trials in patients with life-threatening lung oedema and primary graft dysfunction following lung transplantation, respectively. We are looking forward reviewing the clinical data from both studies in just a few weeks from today" Dr. Fischer added.

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Notes to Editors:

About APEPTICO GmbH (www.apeptico.com)

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 general risks associated with gene- and cell-technologies. APEPTICO makes use of its technology platforms PEPBASE$^{(TM)}$ and PEPSCREEN$^{(TM)}$ to significantly reduce cost and to shorten time to market.

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 results an accelerated lung oedema clearance in the airspace. Comprehensive research and development conducted by APEPTICO has demonstrated that AP301 peptides are effective in animal models of various forms of pulmonary oedema, including high altitude pulmonary oedema, acute lung injury / acute respiratory distress syndrome, pneumonia, influenza virus lung infection, and lung transplantation. Currently, AP301 is subject to two Phase IIa clinical studies for the treatment of patients suffering from life-threatening oedematous respiratory failure and primary graft dysfunction following lung transplantation, respectively.

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 two to four weeks. Currently, no specific drug treatment exists for patients suffering from hyper-permeability-caused lung oedema.

About Primary Graft Dysfunction

Primary Graft Dysfunction (PGD) (Ischemia Reperfusion Injury, IRI) 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 (DAD) on pathology. PGD occurs in approximately 20% of lung transplant recipients and patients face prolonged ventilation, prolonged stays in the ICU and the hospital overall, increased medical costs, and increased risk of morbidity and mortality. Currently, no specific drug treatment exists for patients suffering primary graft dysfunction following lung transplantation.

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PRESS RELEASE

APEPTICO announces a licensing agreement for PEPBASE(TM) with Chem Tech Research Incorporation

Vienna, Austria, October 23, 2013 - APEPTICO, a privately-held biotechnology company developing peptide drugs, today announced that it has entered into a license agreement with Chem Tech Research Incorporation (C-TRI), where APEPTICO will provide C-TRI with a non-exclusive license to APEPTICO's database PEPBASE(TM). Under terms of the Agreement, APEPTICO will receive a license fee and annual payments from C-TRI for data base updates.

APEPTICO (Vienna, Austria) is a clinical stage biotechnology company in Austria that develops new peptide-based medicinal products for therapeutic and prophylactic treatment of various severe forms of pulmonary oedema. C-TRI (Seoul, Korea) is a research-oriented pharma company which focuses on developing new drugs and medicines.

PEPBASE(TM) is a unique research database of human therapeutic proteins. The protein therapeutics included in PEPBASE(TM) are manufactured by recombinant DNA technology and have received marketing authorisation in the EU or US for medicinal use in humans. For each protein a specific profile is established, based on preclinical and clinical data, supported by structural, functional and biochemical data, in an attempt to link structural and therapeutically relevant properties on a single platform. As a consequence of this strategy, therapeutic peptides which mimic functional domains of these human proteins are also described in PEPBASE(TM). Protein profiles also include developmental, manufacturing and regulatory information.

"We are very pleased to enter into this agreement with C-TRI, a Korean leader in peptide chemistry and biotechnology", stated Bernhard Fischer, Chief Executive Officer of APEPTICO. "APEPTICO's database PEPBASE(TM) represents an unique research tool for C-TRI and will make a significant contribution to our new drug development program" commented Kim Wan-joo, Chief Executive Officer of C-TRI.

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About C-TRI (http://www.c-tri.co.kr)
C-TRI is a research-oriented pharmaceutical company which has focused on developing new drugs and medicines ever since its establishment in 1998. The company vision is to become the number one company in Korea in life science. C-TRI is actively growing in next-generation peptide drugs, anti-viral drugs and ionic liquids.

About PEPBASE(TM)
PEPBASE(TM) is APEPTICO's a unique database of human therapeutic proteins. The protein therapeutics included in PEPBASE(TM) are manufactured by recombinant DNA technology and have received marketing authorisation in the EU or US for medicinal use in humans. For each protein a specific profile is established, based on preclinical and clinical data, supported by structural, functional and biochemical data, in an attempt to link structural and therapeutically relevant properties on a single platform. As a consequence of this strategy, therapeutic peptides which mimic functional domains of these human proteins are also described in PEPBASE(TM). Protein profiles also include developmental, manufacturing and regulatory information.

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PRESS RELEASE

APEPTICO accelerates its clinical development program with a research grant from the Austrian Research Promotion Agency (FFG)

Vienna, Austria, July 8, 2013 - APEPTICO, a privately-held biotechnology company developing peptide drugs based on its PEPBASE™ discovery technology, today announced that it has received a research grant worth more than EUR 500,000 from the Austrian Research Promotion Agency (FFG) to accelerate the clinical assessment of the AP301 peptide in patients following lung transplantation.

AP301 is synthetic peptide which has been shown in animal studies in rats and pigs following application by inhalation of the nebulised compound, to prevent and treat ischemia reperfusion injury, to significantly improve gas exchange in pre-damaged donor lungs and to activate lung oedema reabsorption. Until today, no medicinal product has been specifically authorized by medicines agencies for prevention and treatment of primary graft dysfunction / ischemia reperfusion injury in the lung following lung transplantation.

The research grant to APEPTICO results from the FFG recently established research promotion scheme “KLIPHA”. “KLIPHA” specifically aims to enable research-driven companies in Austria to perform phase I and phase II clinical studies with their new molecules. APEPTICO will use the FFG grant for its phase IIa “Pilot study to investigate the clinical effect of orally inhaled AP301 on treatment of primary graft dysfunction (PGD) in mechanically ventilated patients after primary lung transplantation” which started last month at the Medical University Vienna / Vienna General Hospital, Austria.

"We are very pleased that the Austrian Research Promotion Agency (FFG) supports us in our efforts to access the AP301 peptide in this orphan clinical indication” said Bernhard Fischer, CEO of APEPTICO. “Prevention and treatment of primary graft dysfunction represents an unmet medical need as no specific therapy or medicinal product has been approved so far for this life-threatening condition. Having successfully completed our Phase I clinical trial in 2011, this is our second Phase II clinical study in pulmonary patients. We initiated a Phase II clinical study in patients suffering from oedematous respiratory failure in summer 2012 and the new clinical study in lung transplantation patients broadens the therapeutic application of our lead compound AP301.”

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About AP301 peptide family
AP301 and derived peptides are synthetic peptide molecules whose structures are based on naturally occurring motifs. 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 results an accelerated lung oedema clearance in the airspace. Comprehensive research and development conducted by APEPTICO has demonstrated that AP301 peptides are effective in animal models of various forms of pulmonary oedema, including high altitude pulmonary oedema, acute lung injury / acute respiratory distress syndrome, pneumonia, influenza virus lung infection, and lung transplantation. AP301 is subject to a Phase IIa clinical study for the treatment of patients suffering from life-threatening oedematous respiratory failure and subject to a Phase IIa clinical study for the treatment of Primary Graft Dysfunction in patients following lung transplantation.

About Primary Graft Dysfunction
Primary Graft Dysfunction (PGD) / Ischemia Reperfusion Injury (IRI) 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 (DAD) on pathology. PGD occurs in approximately 20% of lung transplant recipients and patients face prolonged ventilation, prolonged stays in the ICU and the hospital overall, increased medical costs, and increased risk of morbidity and mortality.

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PRESS RELEASE

APEPTICO initiates phase II clinical trial with AP301 in patients with primary graft dysfunction following lung transplantation

Vienna, Austria, April 17, 2013 - APEPTICO, a privately-held biotechnology company developing peptide drugs based on its PEPBASE™ discovery technology, today announced that the Ethics Committee of the Medical University of Vienna has approved the company's application to perform a phase IIa clinical study in male and female patients following lung transplantation to investigate the clinical effect of repetitive orally inhaled doses of AP301 on primary graft dysfunction.

AP301 is synthetic peptide which has been shown in animal studies in rats and pigs following application by inhalation of the nebulised compound, to prevent and treat ischemia reperfusion injury, to significantly improve gas exchange in pre-damaged donor lungs and to activate lung oedema reabsorption. Until today, no medicinal product has been specifically authorized by medicines agencies for prevention and treatment of primary graft dysfunction / ischemia reperfusion injury in the lung following lung transplantation.

The interventional, randomized, placebo-controlled, parallel-group study entitled "Pilot study to investigate the clinical effect of orally inhaled AP301 on treatment of primary graft dysfunction (PGD) in mechanically ventilated patients after primary lung transplantation" will be conducted at the Vienna General Hospital and the Medical University of Vienna, Austria. Immediately after lung transplantation, patients will be screened for early signs of primary graft dysfunction. Patients who are included into the study will receive doses of AP301 or matching placebo converted into an aerosol by state-of-the-art nebuliser technology over a period up to 7 days.

"We are very pleased that the Ethics Committee has approved our study" said Bernhard Fischer, CEO of APEPTICO. "Prevention and treatment of primary graft dysfunction represents an unmet medical need as no specific therapy or medicinal product has been approved so far for this life-threatening condition. Having successfully completed our Phase I clinical trial in 2011, this is our second Phase II clinical study in pulmonary patients. We initiated a Phase II clinical study in patients suffering from oedematous respiratory failure (ALI/ARDS) in summer 2012 and the new clinical study in lung transplantation patients broadens the therapeutic application of our lead compound AP301."

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PRESS RELEASE

APEPTICO releases significant scientific results of its industry-academia collaboration network

Vienna, Austria, 31st January, 2013: Apeptico Forschung und Entwicklung GmbH announced that the recent publication of an article in the journal Pulmonary Pharmacology and Therapeutics, describing the effect of APEPTICO's lead compound, AP301, in primary dog, pig and rat cells, marked the culmination of another successful year in the Company's R&D programme.

APEPTICO's research programme comprises a network of collaborative projects with research groups in academic and clinical university departments both in Austria and abroad. The work published this week in Pulmonary Pharmacology and Therapeutics (http://www.ncbi.nlm.nih.gov/pubmed/23313096) is the result of cooperation between APEPTICO and research groups at the Department of Pharmacology and Toxicology of the University of Vienna and the Clinic for Small Animal Surgery of the University of Veterinary Medicine in Vienna. The study describes the isolation of alveolar cells from dog, pig and rat lungs and their application in electrophysiological experiments. For the first time it was shown that APEPTICO's lead compound AP301 exerts a current-enhancing effect in freshly-isolated alveolar cells from dog and pig lungs.

Other highlights of APEPTICO's collaborative research efforts over the last 12 months include: Demonstration of the beneficial effect of AP301 application in a pig model of acute lung injury in a collaborative research project with the Medical Center of the Johannes Gutenberg-University, Mainz, Germany; this work was published in the journal Acta Anaesthesiologica Scandinavica (http://www.ncbi.nlm.nih.gov/pubmed/23216436); Publication in the Journal of Chromatography (http://www.ncbi.nlm.nih.gov/pubmed/23122396) of a bioanalytical study of AP301 undertaken in cooperation with 'pharm-analyt Labor' located in Baden, Austria; Presentation at the American Thoracic Society conference, held in San Francisco, California, of the results of a collaborative study conducted by research groups in Shanghai, China, showing that AP301 attentuates high altitude pulmonary oedema (HAPE) in rats; Further progress in elucidation of the mechanism of action of AP301 and its activating effect on the epithelial sodium channel (ENaC) was communicated at the annual meeting of the Austrian Peptide Society, where the latest results of APEPTICO's ongoing research initiative with scientists at the Department of Pharmacology and Toxicology of the University of Vienna were presented; Completion of a collaborative research project with the Department of Thoracic Surgery of Vienna Medical University, aimed to improve lung transplantation including *ex vivo* lung perfusion of donor lungs; Establishment of a joint research effort with scientists at the Roslin Institute, University of Edinburgh, Scotland, to investigate combination therapy for better treatment of influenza infections.

Dr. Bernhard Fischer, CEO of APEPTICO, commented: "2012 was another productive year in the R&D programme of APEPTICO, illustrating that the Company's strategy of investigating the mechanism of action of its lead compound AP301 through a network of research efforts, is bearing fruit." Dr. Fischer continued: "In both the cell-based electrophysiological studies and the pre-clinical models of lung injury, the role of AP301 in improving alveolar fluid clearance and lung function, thereby reducing oedema, has been clearly demonstrated, paving the way for future application of AP301 in other areas such as HAPE and lung transplantation." AP301 has successfully completed Phase I and is currently undergoing Phase II clinical trials; the clinical trials have been undertaken in collaboration with the Departments of Anaesthesiology and Clinical Pharmacology of the Medical University of Vienna.

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PRESS RELEASE

APEPTICO granted Orphan Drug Designation by EMA and FDA for development compound AP301 for treatment of High Altitude Pulmonary Oedema

18th January, 2013, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing novel peptide-based drugs, today announced that its development compound AP301 has been granted orphan-drug designation by the Committee for Orphan Medicinal Products (European Medicines Agency, EC) and by the Office of Orphan Product Development (Food and Drug Administration, USA) for the clinical indication "treatment of High Altitude Pulmonary Oedema".

High Altitude Pulmonary Oedema (HAPE) is a life-threatening complication of rapid ascent to altitudes higher than 3,000 meters. HAPE represents a non-cardiogenic pulmonary oedema that usually occurs within the first 2–5 days after arrival at high altitude. HAPE is a life-threatening condition with a mortality rate of approx. 25%.

Until today, no drug has been registered, either in Europe or the USA, for prevention and/or treatment of HAPE. HAPE is a life-threatening condition that may affect individuals of any geographic origin when travelling from low to high altitude locations. APEPTICO's synthetic peptide is the first ever compound receiving orphan drug designation for this indication.

Dr. Bernhard Fischer, CEO of APEPTICO commented: "I am pleased that both the European Medicines Agency and the Food and Drug Administration have approved our application for orphan drug designation for AP301 for treatment of High Altitude Pulmonary Oedema. Until today there exists no approved treatment for this life-threatening condition in which the airspace in the lung becomes flooded with body fluids preventing normal gas exchange due reduced air pressure and decreased oxygen supply at high altitude level. Taking into account the steadily increasing mobility of people worldwide, HAPE may affect increasing numbers of tourists and workers in high altitude regions, such as the Alps and Pyrenees in Europe, the Himalayas in Asia, and mountains in Alaska in the USA or the Andes in South America." Dr. Fischer added, "HAPE was first described in great detail in a series of reports from an expedition to the Mont Blanc massive in 1891, having been published in the Swiss "Neue Zürcher Zeitung" in August and September 1891. During this Mont Blanc expedition, at least four members of the team suffered from HAPE, one of whom,the expedition's medical doctor, Dr. Jacotte, unfortunately died at an altitude of about 4,000 meters. With our innovation we hope to make an important contribution to the field of environmental medicine by improving the patient's condition and avoiding an unfortunate outcome, if affected by HAPE."

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High Altitude Pulmonary Oedema

High altitude pulmonary oedema (HAPE) is a life-threatening complication of rapid ascents to altitudes higher than 3,000 m that usually occurs within the first 2–5 days after arrival at high altitude. At 3,000 m, the standard barometric pressure is 72kPa (537 mmHg). This means that there is only 71% of the oxygen available at sea level. The reduced partial oxygen pressure in the atmosphere results in a drop of the alveolar and arterial oxygen pressure. Above 3,000 m the oxygen saturation in the blood (SaO2) drops below 90%. During exercise and sleep hypoxia is increased. Furthermore temperature and atmospheric humidity decrease as well. In sum, climatic and environmental changes lead to exaggerated pulmonary hypertension leading to vascular leakage through over-perfusion, stress failure, or both. Individual susceptibility, rate of ascent, and pre-exposure to high altitude are major, independent determinants of high altitude pulmonary oedema.

About Orphan Drugs

An orphan drug is a pharmaceutical agent that specifically treats a rare medical condition, the condition itself being referred to as an orphan disease. Both European and USA orphan drug legislation aim to encourage pharmaceutical companies to develop drugs for rare diseases. Under the law, companies that develop such a drug for an orphan disorder gain marketing exclusivity for 10 years (EU) and 7 years (USA) after marketing approval.

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