

# APEPTICO presents its lead product AP301 at BIO-Europe 2009 in Vienna, Austria

01<sup>st</sup> November September, 2009, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing the novel peptide-based drug AP301 for the treatment of the life threatening disease "Acute Lung Injury", announced today that it will participate at the 15<sup>th</sup> BIO-Europe International Partnering Conference which starts on 2<sup>nd</sup> November 2009 in Vienna, Austria. APEPTICO will be in the Austrian Biotech Pavilion conducting pre-scheduled face-to-face meetings.

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, pharmacodynamically 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 costs and time-to-market are significantly reduced compared to biomolecules manufactured by the recombinant development process.

APEPTICO's lead compound AP301 is a short synthetic peptide. AP301 activates alveolar liquid clearance and counteracts microbial toxins (sepsis) and reactive oxygen species (ROS). It is the first compound that specifically treats pulmonary oedema. AP301 is being developed by APEPTICO for the treatment of Acute Lung Injury (ALI) / Acute Respiratory Distress Syndrome (ARDS). ALI and its most catastrophic form ARDS are life-threatening conditions affecting more than 500,000 patients annually in the western world. The mortality rate of ALI / ARDS is 40 to 60%.

Today, no specific medicine has been approved in Europe or the USA for the treatment of ALI / ARDS. To overcome this deficit, AP301 has received Orphan Drug Designation by the European Commission.

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#### **Notes to Editors:**

#### About APEPTICO GmbH

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APEPTICO's development platform PEPBASE<sup>TM</sup> 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 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 toxinand reactive oxygen species-induced hyper-permeability. AP301 causes no toxic side effects.

#### 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 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.

#### About BIO-Europe International Partnering Conference

This year the 15<sup>th</sup> BIO-Europe International Partnering Conference takes place in Vienna. BIO-Europe is the largest partnering conference in Europe. Annually leading dealmakers from biotech, pharma and finance along with the most exciting emerging companies are attracted to the conference. APEPTICO, as an innovative young biotechnology company, uses the concentrated presence of Europe's Biotech scene for productive partnering and to present itself in the Austrian Biotech Pavilion.

## Contact

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# APEPTICO presents its lead product AP301 at the Annual Congress of the European Respiratory Society in Vienna, Austria

08<sup>th</sup> September, 2009, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing a novel peptide-based drug for the treatment of the life threatening disease "Acute Lung Injury" today announced, that it will present its most recent scientific results for APEPTICO's lead compound AP301 at the Annual Congress of the European Respiratory Society which starts on 12<sup>th</sup> September 2009 in Vienna, Austria.

At the Annual Congress of the European Respiratory Society (ERS), Prof. Dr. Rudolf Lucas, co-founder and Chief Scientific Officer of APEPTICO Forschung und Entwicklung GmbH, will present the most recent results for APEPTICO's lead compound AP301 to the audience of international clinicians and scientists. AP301, which recently received Orphan Drug Designation from the European Commission, is being developed by APEPTICO Forschung und Entwicklung GmbH for the treatment of the life threatening disease "Acute Lung Injury". Prof. Lucas will give oral presentations on 13<sup>th</sup> September entitled "The lectin-like domain of TNF improves lung function after rat lung transplantation - potential role for a reduction in Reactive Oxygen Species generation" and on 15<sup>th</sup> September entitled "Novel regulators of alveolar liquid clearance".

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 ERS Congress organising committee is giving Professor Rudolf Lucas the opportunity to present our most recent results for AP301 in the context of two scientific symposia. In addition, at the invitation of the ERS Congress organisers, APEPTICO will be presenting the development stage biotechnology company in the scientific exhibition area. There are only a handful of companies in Austria developing biotechnology-based medicine for the treatment of pulmonary diseases." "Please visit APEPTICO at booth D.06 during the ERS Congress" added Dr. Fischer.

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#### About APEPTICO Forschung und Entwicklung GmbH

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#### About Acute Lung Injury (ALI)

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.

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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.

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

20<sup>th</sup> 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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#### PRESSE MITTEILUNG

# APEPTICO GmbH erhält Preis anlässlich der Verleihung des "Venture Capital & Private Equity Award Österreichs"

09. Juni 2009, Wien, Österreich: APEPTICO Forschung und Entwicklung GmbH teilt mit, dass das Unternehmen anlässlich der Verleihung des "Venture Capital & Private Equity Award Österreichs" mit einem Preis ausgezeichnet wurde. Dieser Preis wurde durch den "Styria Börse Express" und die "Junge Industrie" verliehen und stellt eine Anerkennung für die kürzlich abgeschlossene Finanzierung des Unternehmens durch Investoren und Österreichische Fördergeber dar.

Der Gedanke des 2005 erstmals vergebenen "Venture Capital & Private Equity Award Österreichs" ist es, mittels eines einzigartigen Preises Venture Capital und Private Equity Aktivitäten der breiteren Öffentlichkeit näher zu bringen, erfolgreiche und vorbildhafte VC/PE-Deals auszuzeichnen und die handelnden Personen der Kapitalgeber als auch deren Beteiligungsunternehmen bekannter zu machen.

APEPTICO erhielt diesen Preis zusammen mit seinen Investoren, The BioScience Ventures Group AG und dem Schweizer Privatinvestor Dr. Jürg Geigy, sowie mit den Österreichischen Fördergebern Forschungsförderungsgesellschaft mbH und INiTS Universitäres Gründerservice Wien GmbH.

Der "Venture Capital & Private Equity Award Österreichs" wird auf Empfehlung einer hochrangig besetzten Jury vergeben, welcher u.a. Herr Reinhold Mitterlehner, Bundesminister für Wirtschaft, Familie und Jugend, Herr Christian Drastil, Geschäftsführer der Styria Börse Express GmbH, Herr Markus Beyrer, Generalsekretär der Industriellenvereinigung, Markus Fellner, Partner bei Fellner Wratzfeld & Partner Rechtsanwälte GmbH, Herr Richard Schenz, Berater des Finanzministers für Fragen der Kapitalmarktentwicklung und der Corporate Governance, angehören.

Dr. Bernhard Fischer, CEO von APEPTICO kommentierte: "Wir sind sehr glücklich, dass unsere kürzlich abgeschlossene Finanzierungsrunde offenbar in Österreich Maßstäbe setzt. APEPTICO ist ein junges, forschendes Biotechnologie-Unternehmen, welches ideale Investoren und Fördergeber mit einem neuartigen Entwicklungskonzept überzeugen konnte."

#### Zusätzliche Informationen für Herausgeber

# Über APEPTICO Forschung und Entwicklung GmbH

APEPTICO Forschung und Entwicklung GmbH (<a href="www.apeptico.com">www.apeptico.com</a>) konzentriert sich auf die Erkennung und Entwicklung von pharmakologisch wirksamen Nano-Peptiden - auf der Basis bio-aktiver Makromoleküle - zur Entwicklung von innovativen Arzneimitteln für die klinische und therapeutische Behandlung von schweren und chronischen Erkrankungen. Derzeit entwickelt APEPTICO das biologisch aktive Peptide "AP301" zur Behandlung des Akuten Lungenschadens (ALI).

# Über The BioScience Ventures Group AG

The BioScience Ventures Group (BSVG, <a href="www.bsvg.com">www.bsvg.com</a>, München, Deutschland) ist ein Zusammenschluss von Business Angels, der sich exklusiv auf Investments im Biotechnologie-Frühhphasen-Bereich spezialisiert hat und unterstützt das Drug Development, Design und die Durchführung präklinischer und klinischer Studien, insbesondere im Bereich von biologischen Wirkstoffen.

# Über Forschungsförderungsgesellschaft mbH

Die Österreichische Forschungsförderungsgesellschaft mbH (www.ffg.at) ist die nationale Förderstelle für anwendungsorientierte und wirtschaftsnahe Forschung in Österreich. Sie unterstützt österreichische Unternehmen, Forschungsinstitutionen, Forscherinnen und Forscher mit einem umfassenden Angebot von Dienstleistungen und Förderungsprogrammen der öffentlichen Hand."

## Über INiTS Universitäres Gründerservice Wien GmbH

Die INiTS Universitäres Gründerservice Wien GmbH (<a href="www.inits.at">www.inits.at</a>) ist das Wiener Zentrum des AplusB-Programms des Infrastrukturministeriums. INiTS ist eine Gesellschaft des Zentrums für Innovation & Technologie der Stadt Wien (ZIT), der Universität Wien und der Technischen Universität Wien. INiTS fördert Innovationen aus den Bereichen Informationsund Kommunikationstechnik, Life Science und anderen Forschungsbereichen

#### **Kontakt**

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#### **APEPTICO GmbH closes seed financing round**

29<sup>th</sup> May, 2009, Vienna, Austria: APEPTICO, a biotechnology company developing novel peptide-based drugs, announced completion of a seed financing round. The EUR 1 Mio equity financing round was led by The BioScience Ventures Group AG (BSVG, www.bsvg.com, Munich/Germany) and included the participation of the Swiss business angel Dr. Jürg Geigy. Both, BSVG and Dr. Geigy are specialised in early stage investments in the biotech industry. The completion of the financing round entitled APEPTICO to receive a grant of EUR 1.2 Mio from the Austrian Research Promotion Agency (FFG).

APEPTICO will use the allocated capital to push ahead the pre-clinical development of its lead compound AP301. AP301 is a short and chemically synthesized cyclic peptide that is being developed for the treatment of pulmonary oedema in Acute Lung Injury (ALI) / Acute Respiratory Distress Syndrome (ARDS). Both, ALI and ARDS are life-threatening conditions with high mortality rates, and no specific therapeutic or prophylactic drug has been approved by the EMEA or FDA until now. AP301 has additional significant potential in other lung diseases, such as pneumonia and lung transplantation. Patents covering AP301 were recently granted in the EU and the USA.

APEPTICO plans to nominate further molecules for formal pre-clinical development in the future and to broaden application of its PEPBASE<sup>TM</sup> discovery platform in the field of peptide drug identification and validation.

Dr. Bernhard Fischer, CEO of APEPTICO commented: "We are delighted to have secured seed financing, especially at this time of global economic crisis. The commitment of the BSVG and Dr. Jürg Geigy demonstrates the great confidence of our investors in APEPTICO's drug development concept."

#### **Notes to Editors**

#### About APEPTICO GmbH

APEPTICO is a privately-held pre-clinical stage 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 and development cost, and time to market is significantly reduced if compared to the recombinant development process of biomolecules.

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Prior to the seed financing round, APEPTICO has received pre-seed funding from Austria Wirtschaftsservice (AWS), from Forschungsförderungsgesellschaft (FFG) and from INITS Universitäres Gründerservice in Vienna, Austria.

#### 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 as aerosol using standard nebuliser systems. AP301 has been designed for the treatment of Acute Lung Injury (ALI), Acute Respiratory Distress Syndrom (ARDS), Ventilator Associated Lung Injury (VALI), Lung Transplantation, Pneumonia and other form of the permeability oedema. ALI and ARDS are life-threatening diseases associated with mortality rates of 30% to 60%. Currently, no specific treatment is available. AP301 activates lung oedema reabsorption and protects both endothelial and epithelial lung tissue from microbial toxin- and reactive oxygen species-induced hyper-permeability.

#### Contacts

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# March 26th, 2009. Medical breakthrough for treatment of Acute Lung Injury

**Vienna, Austria** – Based on intensive research and comprehensive *in-vitro* and *in-vivo* studies APEPTICO Forschung und Entwicklung GmbH, a Vienna development stage biotechnology company, has clarified the mode of action of its development compound AP301. Up to date there exists no approved drug molecule for the treatment of Acute Lung Injury. Up to 100,000 patients in Europe could benefit from the new discovery.

In collaboration with the Medical Collage of Georgia (Augusta, USA) the research team of APEPTICO has developed a new concept for treating the life-threatening condition Acute Lung Injury / Acute Respiratory Distress Syndrome.

Acute Lung Injury affects approx. 100.000 patients per year in Europe. Today, no direct treatment is possible due to lack of effective medicine. The mortality rate for Acute Lung Injury ranges from 30% to 60%. According to the Austrian Ministry of Health several hundred patients die each year of Acute Lung Injury, which is a much higher figure in comparison to AIDS.

Acute Lung Injury is characterised by tissue injury of the lung followed by formation of a lung oedema as fluid penetrates from blood capillaries into lung tissue. Tissue damage and lung oedema prevent normal gas exchange, i.e. oxygen from the breathing air is not delivered to the blood. To save patients lives instant intensive care treatment is needed.

By making use of PEPBASE<sup>TM</sup> - APEPTICO's own database - the synthetic peptide AP301 was designed based on a structural element of a human protein. Most recent research data generated by APEPTICO's co-founder Prof. Rudolf Lucas at the Medical Collage of Georgia revealed fundamental aspects of the mode of action of AP301.

The official name of the development drug AP301 has already been defined by the European Medicines Agency as "Human Tumour Necrosis Factor-derived Peptide".

"At the beginning, we had two different options for manufacture of the peptide AP301, either by biotechnology or by chemical synthesis. We favoured the chemical synthesis as this way saves a lot of development time and reduces cost significantly" comments Univ.-Doz. Dr. Bernhard Fischer, CEO of APEPTICO. "We aim to assist patients with Acute Lung Injury as fast as possible".

Most recent research data demonstrate that AP301 counter-acts the hyper-permeability of lung endothelial and epithelial cells and tissues caused by reactive oxygen species and bacterial toxins. AP301 reduces the phosphorylation of myosin light chain and inhibits the activation of protein kinase C. This in turn leads to activation of the apical sodium ion channel in pulmonary alveoli. Taken together, AP301 leads to regression of the lung oedema and protects the lung tissue from further injury.

Further animal studies demonstrated that besides application of AP301 for Acute Lung Injury, further treatment options are possible. AP301 increases oxygen supply after lung transplantation and is effective in treatment of bacterial or viral pneumonia.

Currently, APEPTICO focuses on securing next round of financing. "We have already worked out a model for financing and shareholding with investors", says CEO Bernhard Fischer. Despite of the critical situation of the financial market APEPTICO is confident that Austrian business angel and private and institutional investors invest into APEPITICO.

Since November 2007 APEPTICO is hosted by INITS, the Vienna academic ApluB center. INITS actively supports research teams and new company projects by providing business development services, infrastructure and start-up grants. INITS aims to transform basic research results into company formations.

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