

PRESS RELEASE

The Committee for Orphan Medicinal Products of the European Medicines Agency grants orphan drug designation to APEPTICO's development compounds AP301 and AP318 for treatment of for treatment of Pseudohypoaldosteronism Type 1B

1st December 2015, Vienna, Austria: APEPTICO Forschung und Entwicklung GmbH, a biotechnology company developing novel peptide-based drugs, today announced that its development compounds AP301 (INN: Solnatide) and AP318 have been granted orphan drug designation by the Committee for Orphan Medicinal Products of the European Medicines Agency for treatment of Pseudohypoaldosteronism Type 1B.

Pseudohypoaldosteronism type 1B (PHA 1B) is an autosomal recessive disorder caused by loss-of-function mutations in the epithelial sodium ion channel (ENaC). This life-threatening condition usually presents in the first weeks of life with severe dehydration, salt wasting and failure to thrive, symptoms which persist into adulthood. Patients often suffer from respiratory infections and may die from potassium overload and cardiac arrest. Currently, no satisfactory method of treatment exists.

This was the first time that a development compound has been granted orphan medicinal product designation for this life-threatening, chronic condition by the European Medicines Agency. APEPTICO's request was based on results from cell-based studies making use of heterologous expression of mutant versions of the human ENaC. The majority of non-clinical data have been generated during scientific collaborations of APEPTICO with Professor Rosa Lemmens-Gruber's team from the Department of Pharmacology & Toxicology of the University Vienna (Vienna, Austria). Genetic manipulation, recombinant expression and electrophysiological techniques were used to demonstrate that AP301 and AP318 restored the sodium transport through mutant, loss-of-function ENaC to normal levels and higher.

Dr. Bernhard Fischer, CEO of APEPTICO commented: "I am very pleased that the European Medicines Agency has approved our application for orphan drug designations for solnatide (laboratory code AP301) and AP318 for treatment of pseudohypoaldosteronism type 1B. Until today there exists no approved therapy for this chronic and life-threatening condition." Dr. Fischer added, "We are very proud to expand the clinical uses of our therapeutic peptides into chronic conditions while we further substantiate the clinical application of AP301 and related synthetic peptides in phase III clinical trials for treatment of the pulmonary permeability oedema in patients with acute respiratory distress syndrome and for treatment of primary graft dysfunction in patients following lung transplantation, both acute life-threatening conditions."

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Notes to Editors:

About APEPTICO Forschung und Entwicklung 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 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 APEPTICO's therapeutic protein structures

APEPTICO's proprietary therapeutic molecules, such as AP301 (INN: solnatide) and AP318 are synthetically manufactured structural equivalents to domains of the human proteins. Liquid and dry powder formulations of such protein structures can be administered into the lung by inhalation of aerosol particles with diameter 5 micrometres or less. Most recently, APEPTICO has successfully completed two Phase II clinical trials with orally inhaled peptides for treatment of patients with pulmonary permeability oedema and ARDS (acute respiratory distress syndrome) and for treatment of patients with primary graft dysfunction following lung transplantation. For both acute and life-threatening conditions no specific drug-based treatments exist so far.

About pseudohypoaldosteronism type 1B (PHA 1B)

Pseudohypoaldosteronism type 1B (PHA 1B) or autosomal recessive pseudohypoaldosteronism type I, is characterized by salt wasting from the kidney, colon, and sweat and salivary glands leading to high concentrations of sodium in sweat, stool, and saliva. The disorder involves multiple organ systems and is especially threatening in the neonatal period. Laboratory evaluation shows hyponatremia, hyperkalemia, and increased plasma renin activity with high serum aldosterone concentrations. Sweat and salivary glands, the distal renal tubule, and colonic mucosa are unresponsive to mineralocorticoids. In addition to severe dehydration, vomiting and failure to thrive occurring in the first weeks of life, the clinical picture may be complicated by cardiac dysrhythmias, collapse, shock or cardiac arrest. An increase in the volume of airway surface liquid leads to frequent respiratory tract manifestations and respiratory tract infections are common in affected children. PHA 1B is severe: no remission has been reported and patients suffer from recurrent life-threatening episodes of salt loss requiring salt supplements and control of hyperkalemia to ensure survival. PHA 1B is transmitted in an autosomal recessive manner and is caused by mutations in the genes coding for the subunits of the amiloride-sensitive sodium channel, ENaC resulting in the expression of mutant, loss-of-function ENaC.

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. 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.

Contact

Prof. Dr. Bernhard Fischer, Chief Executive Officer
APEPTICO Forschung und Entwicklung GmbH
Mariahilferstraße 136, Top 1.1.5
1150 Vienna, Austria
T: +43-664-1432919
F: +43-1-25330337795
E-mail: b.fischer@apeptico.com
URL: www.apeptico.com

PRESS RELEASE

The Committee for Orphan Medicinal Products of the European Medicines Agency grants orphan drug designation to APEPTICO's development compound AP301 for treatment of primary graft dysfunction following lung transplantation

5th October 2015, 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 of the European Medicines Agency for the orphan indication 'treatment of primary graft dysfunction following lung transplantation'.

Primary graft dysfunction (PGD) refers to acute allograft dysfunction within the first 72 h following lung transplantation in the absence of identifiable secondary causes. PGD is characterized by poor oxygenation and low pulmonary compliance; it affects approx. 30% of all lung transplant recipients for whom it represents a significant cause of early morbidity and mortality. Currently, no satisfactory method of treatment exists.

This was the first time that a development compound has been granted orphan medicinal product designation for this life-threatening condition by the European Medicines Agency. APEPTICO's request was based on results from numerous non-clinical studies and excellent results from a phase II clinical trial in lung transplant patients. The majority of non-clinical data have been generated during scientific collaborations of APEPTICO with Professor Rudolf Lucas from the Medical College of Georgia (Georgia Regents University, Augusta, USA) and with Professor Rosa Lemmens-Gruber's team from the Department of Pharmacology & Toxicology of the University Vienna (Vienna, Austria). The phase II "Pilot study to investigate the clinical effect of orally inhaled AP301 on treatment of primary graft dysfunction in mechanically ventilated patients after primary lung transplantation" was conducted by Professor Walter Klepetko's lung transplant team from the Department of Thoracic Surgery of the Medical University Vienna (Vienna, Austria).

Dr. Bernhard Fischer, CEO of APEPTICO commented: "I am very pleased that the European Medicines Agency has approved our application for orphan drug designation for AP301 for treatment of primary graft dysfunction following lung transplantation. Until today there exists no approved therapy for this life-threatening condition." Dr. Fischer added, "We are very proud that Professor Clemens Aigner from the Department of Thoracic Surgery was allowed by the scientific steering committee to present the late breaking clinical data at this year's International Congress of the European Respiratory Society (October 26th 2015, Amsterdam, Netherlands)."

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technology platforms PEPBASE^(TM) and PEPSCREEN^(TM) to significantly reduce cost and to shorten time to market.

About the APEPTICO's therapeutic protein structures

APEPTICO's proprietary therapeutic molecules are synthetically manufactured structural equivalents to domains of the human proteins. Liquid and dry powder formulations of such protein structures can be administered into the lung by inhalation of aerosol particles with diameter 5 micrometres or less. Most recently, APEPTICO has successfully completed two Phase II clinical trials with orally inhaled peptides for treatment of patients with pulmonary permeability oedema and ARDS (acute respiratory distress syndrome) and for treatment of patients with primary graft dysfunction following lung transplantation. Currently, no specific drug treatments exist for both acute and life-threatening pulmonary dysfunctions.

About primary graft dysfunction (PGD)

PGD after lung transplantation represents a multifactorial parenchymal injury and dysfunction to the transplanted lung that develops in the first 72 hours after transplantation in the absence of identifiable secondary causes.

The most common indications for lung transplantation are chronic obstructive pulmonary disease (COPD) including emphysema, idiopathic pulmonary fibrosis and cystic fibrosis. Other indications include alpha1-anti-trypsin deficiency emphysema, idiopathic pulmonary arterial hypertension, and sarcoidosis.

PGD is characterized by poor oxygenation and low pulmonary compliance as the main criterion for the condition, formation of interstitial & alveolar oedema, pulmonary infiltrates on chest radiographs, increased pulmonary vascular resistance, intrapulmonary shunt and acute alveolar injury, as revealed by diffuse alveolar damage (IDAD) on pathology. PGD occurs in approx. 30% of lung transplant recipients and it represents a significant cause of early morbidity and mortality to lung transplant patients.

Contact

Prof. Dr. Bernhard Fischer, Chief Executive Officer

APEPTICO Forschung und Entwicklung GmbH

Mariahilferstraße 136, Top 1.1.5

1150 Vienna, Austria

T: +43-664-1432919

F: +43-1-25330337795

E-mail: b.fischer@apeptico.com

URL: www.apeptico.com

PRESS RELEASE by APEPTICO

Vienna, Austria, June 1st 2015

Vienna, Austria, 1st June 2015: APEPTICO, a privately held biotechnology company developing peptide drugs, today announced that it has succeeded in the technical development of carrier-free protein-only dry powder inhalation particles.

Oral inhalation of medicines by patients represents an alternative delivery route for therapeutic molecules in comparison to intravenous application. For treatment of various lung dysfunctions, small chemical molecules in combination with various carrier compounds are commonly used to acquire inhalable medicines used by patients with so-called dry powder inhalers (DPI). So far, inhalable medicine has been restricted to small molecules, while macromolecules such as proteins and peptides appeared unsuitable to form spherical powder particles with diameters of just a few microns.

By applying a sophisticated process that atomises APEPTICO's proprietary small protein '*Solnatide*' in a spray-drying process, APEPTICO in collaboration with Upperton Ltd. (Nottingham, United Kingdom) and Hovione Ltd. (Loures, Portugal) succeeded in the conversion of *Solnatide* into micrometer scale, spherically shaped, carrier-free dry powder particles that fulfil all the technical requirements for use with a dry powder inhaler. APEPTICO develops *Solnatide* for therapeutic treatment of pulmonary dysfunctions characterised by the presence of a life-threatening lung oedema and injury of the lung tissue. Liquid aerosol formulations of *Solnatide* have been successfully clinically tested in patients with pulmonary permeability oedema and Acute Respiratory Distress Syndrome and in patients with primary graft dysfunction following lung transplantation.

Dr. Bernhard Fischer, CEO of APEPTICO, stated: "In the past *Solnatide* has been inhaled by patients as liquid aerosol particles. The engineering of *Solnatide* dry powder particles to be inhaled by patients with a DPI represents a breakthrough result not only for APEPTICO but for the inhalation medicine industry. Even liquid aerosol formulations of proteins and peptides such as *Solnatide* are very rare in human medicine praxis, but the preparation of micron sized carrier-free dry powder particles for oral inhalation composed exclusively of pure therapeutic peptide seemed impossible until today." "Use of *Solnatide* dry powder inhalation medicine will allow us to apply this therapeutic medicine to additional pulmonary indications and to deliver *Solnatide* to patients without liquid nebuliser device and intubation" Dr. Fischer added.

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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 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 APEPTICO's therapeutic protein structures

APEPTICO's proprietary therapeutic molecules are synthetically manufactured structural equivalents to domains of the human proteins. Liquid formulations of such protein structures can be administered into the lung by inhalation of liquid aerosol droplets of diameter 4 micrometres or less. Most recently, APEPTICO has successfully completed two Phase II clinical trials with orally inhaled *Solnatide* for treatment of patients with pulmonary permeability oedema and ARDS (acute respiratory distress syndrome) and for treatment of patients with primary graft dysfunction following lung transplantation. Currently, no specific drug treatments exist for both acute and life-threatening pulmonary dysfunctions.

About dry powder inhalers

Dry powder inhalers (DPIs) are inhalers that deliver medication in a dry powder form. DPIs are commonly used to treat respiratory diseases such as asthma, bronchitis, emphysema and chronic obstructive pulmonary disease (COPD). Today's DPI formulations consist of micronized chemical drug blended with larger carrier particles, which enhance flow, reduce aggregation, and aid in dispersion. A combination of intrinsic physicochemical properties, particle size, shape, surface area, and morphology affects the forces of interaction and aerodynamic properties, which in turn determine fluidization, dispersion, delivery to the lungs, and deposition in the peripheral airways. When a DPI is actuated, the formulation is fluidized and enters the patient's airways. Presently, therapeutic active chemical drug particles separate from the carrier particles and are carried deep into the lungs, while the larger carrier particles impact on the oropharyngeal surfaces and are cleared.

The conversion of proteins and peptides into carrier-free micron-size particles with fluidization properties and their direct use with DPIs is virtually unknown to patient treatment.

Contact

Univ.-Doz. Dr. Bernhard Fischer, Chief Executive Officer
APEPTICO Forschung und Entwicklung GmbH
Mariahilferstraße 136, Top 1.1.5
1150 Vienna, Austria
T: +43-664-1432919
F: +43-1-25330337795
E-mail: b.fischer@apeptico.com
URL: www.apeptico.com

PRESS RELEASE by APEPTICO

Vienna, Austria, March 3rd 2015

Vienna, Austria, 3rd March 2015: APEPTICO, a privately held biotechnology company developing peptide drugs, today announced that the phase IIa clinical study of AP301-peptide delivered top-line results in the treatment of primary graft dysfunction in patients following lung transplantation.

In lung transplantation (LuTX), a healthy lung from a deceased donor replaces the damaged lung of a patient to increase quality of life or even survival time of the recipient. Despite refinements in lung preservation and improvements in surgical techniques and perioperative care, primary graft dysfunction (PGD) remains a significant cause of early morbidity and mortality after lung transplantation. In addition to significant morbidity and mortality in the early postoperative period, PGD can also be associated with an increased risk of acute rejection that may lead to graft dysfunction in the long term. Currently, there is no effective pharmacotherapy available for treatment of PGD.

The proof-of-concept phase IIa clinical study was conducted at the Departments of Thoracic Surgery and Intensive Care Medicine of the Medical University of Vienna. The primary objective of this interventional, randomised, placebo-controlled study was to assess the clinical effect of orally inhaled AP301-peptide on treatment of PGD in patients after primary lung transplantation in comparison to placebo.

Results from this study showed that oral inhalation of AP301-peptide led to an early resolution of pulmonary oedema, pronounced improvement of gas exchange and normalisation of respiratory parameters, shortening of duration of mechanical ventilation and intensive care treatment, and earlier discharge of patients from hospital, when compared to placebo. On average, AP301-peptide treated patients were weaned from mechanical ventilation 1.5 days earlier, ICU treatment was terminated 3 days earlier and patients were discharged from the hospital up to 5 days earlier.

Dr. Bernhard Fischer, CEO of APEPTICO, stated: “We are very proud to have achieved this significant clinical goal. The results of this clinical study in lung transplantation strongly support previous findings from our previous trial in mechanically ventilated patients with pulmonary permeability oedema and ARDS. Our AP301-peptide is a very effective compound mediating recovery of normal lung function following lung injury and ischemia reperfusion injury. This major success would not have been possible without the enthusiastic support of the clinical study teams of Professor Walter Klepetko and Professor Clemens Aigner (Division Thoracic Surgery), and Professor Roman Ullrich and Professor Klaus Markstaller (Division of General Anaesthesia and Intensive Care Medicine) of the Medical University Vienna.” “Our excellent scientific and clinical data are the basis for partnership with global and specialised pharmaceutical and biotech companies” Dr. Fischer added.

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About APEPTICO GmbH

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About the APEPTICO's synthetic protein structures

APEPTICO's molecules are synthetically manufactured structural equivalents to domains of the human Tumour Necrosis Factor- α . The protein structures are water-soluble and can be administered into the lung by inhalation of liquid aerosol droplets of diameter 4 μm or less. Most recently, APEPTICO has successfully completed two phase II clinical trials with orally inhaled peptides for treatment of pulmonary permeability oedema and treatment of primary graft dysfunction following lung transplantation.

Currently, no specific drug treatment exists for life-threatening conditions such as pulmonary permeability oedema and ARDS, primary graft dysfunction following lung transplantation and high altitude pulmonary oedema.

APEPTICO's synthetic molecules have been granted orphan drug designations for various life-threatening pulmonary conditions by the European Medicines Agency (EMA) and by the Food and Drug Agency (FDA).

About lung transplantation and primary graft dysfunction

Approx. 5,000 lung transplantations are performed every year in Europe and North America according to the International Registry for Heart and Lung Transplantations. Lung transplantation is considered a rare event and affects mainly patients with severe COPD/emphysema, idiopathic pulmonary fibrosis, cystic fibrosis, alpha-1 deficiency, idiopathic pulmonary arterial hypertension, bronchiectasis, connective tissue disease and obliterative bronchiolitis.

Primary graft dysfunction occurs in approx. 20% of lung transplant recipients within the first 72 hours. PGD 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. With 28% primary graft dysfunction is the main cause of death in the first 30 days following lung transplantation.

Contact

Univ.-Doz. Dr. Bernhard Fischer, Chief Executive Officer

APEPTICO Forschung und Entwicklung GmbH

Mariahilferstraße 136, Top 1.1.5

1150 Vienna, Austria

T: +43-664-1432919

F: +43-1-25330337795

E-mail: b.fischer@apeptico.com

URL: www.apeptico.com

PRESS RELEASE by APEPTICO

Vienna, Austria, February 18th 2015

Vienna, Austria, 18th February 2015: APEPTICO, a privately-held biotechnology company developing synthetic protein structures, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has confirmed the phase III clinical development strategy for APEPTICO's AP301-peptide in the orphan condition Acute Respiratory Distress Syndrome.

APEPTICO announced today that it has received scientific advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) for the forthcoming phase III clinical trial of the AP301-peptide in the life-threatening and orphan condition Acute Respiratory Distress Syndrome (ARDS). According to the written advice, APEPTICO is encouraged to initiate a two-part phase III double blind clinical trial. The CHMP also confirmed that no further non-clinical studies are needed to continue the clinical development program.

The CHMP suggests that in the first part of the phase III clinical study aspects of dose finding should be incorporated. The formal proof of efficacy should be demonstrated in the second part of the phase III clinical trial. In addition, the CHMP would agree that a positive first part phase III study could be a basis to apply for conditional marketing approval.

In a setting with co-primary endpoints CHMP could accept a benefit demonstrated with “ventilator-free days” (VFD) as long as convincing evidence is also provided that “all-cause-mortality at day 28” is not adversely affected by the AP301-peptide.

Bernhard Fischer, CEO of APEPTICO commented “We are very pleased that the EMA has given us constructive scientific advice and provided protocol assistance to the forthcoming clinical development of AP301-peptide.” “A potential conditional marketing approval of AP301-peptide following successful completion of a first-part phase III clinical trial will significantly speed up both the completion of the entire phase III trial and the final approval process of AP301-peptide in Europe” he added.

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About APEPTICO GmbH

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About the APEPTICO's synthetic protein structures

APEPTICO's molecules are synthetically manufactured structural equivalents to domains of the human Tumour Necrosis Factor- α . The protein structures are water-soluble and can be administered into the lung by inhalation of liquid aerosol droplets of diameter 4 μm or less. Most recently, APEPTICO has successfully completed two phase II clinical trials with orally inhaled peptides for treatment of pulmonary permeability oedema and treatment of primary graft dysfunction following lung transplantation. APEPTICO's synthetic molecules have been granted orphan drug status various life-threatening condition by the European Medicines Agency (EMA) and by the Food and Drug Agency (FDA).

About the AP301-peptide / TIP-peptide

The AP301-peptide (synonym to TNF-derived TIP-peptide) is a synthetically manufactured molecule whose structure bases on the lectin-like domain of the human Tumour Necrosis Factor α . The AP301 peptide is 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. APEPTICO's most recent clinical phase II proof-of-concept study (ClinicalTrials.gov ID NCT01627613) demonstrated that orally inhaled AP301-peptide activates alveolar liquid clearance in mechanically ventilated patients with pulmonary permeability oedema and ARDS.

Comprehensive research and development studies conducted by the APEPTICO research consortium demonstrated that AP301-peptides are effective therapeutic molecules in various forms of pulmonary oedema, such as pulmonary permeability and hydrostatic oedema, high altitude pulmonary oedema, pulmonary oedema associated with acute lung injury / acute respiratory distress syndrome, pulmonary oedema resulting from pneumonia and sepsis, and primary graft dysfunction following lung transplantation.

Currently, no specific drug treatment exists for life-threatening conditions such as pulmonary permeability oedema and ARDS, primary graft dysfunction following lung transplantation and high altitude pulmonary oedema.

APEPTICO's AP301 has received orphan drug designation status for various life-threatening conditions by the European Commission and European Medicines Agency (EMA) and by the Food and Drug Agency (FDA).

Contact

Univ.-Doz. Dr. Bernhard Fischer, Chief Executive Officer

APEPTICO Forschung und Entwicklung GmbH

Mariahilferstraße 136, Top 1.1.5

1150 Vienna, Austria

T: +43-664-1432919

F: +43-1-25330337795

E-mail: b.fischer@apeptico.com

URL: www.apeptico.com

PRESS RELEASE by APEPTICO

Vienna, Austria, January 2nd 2015

Vienna, Austria, 2nd January 2015: APEPTICO, a privately-held biotechnology company developing synthetic protein structures, today announced that it has been awarded a research grant by the Wellcome Trust under the Pathfinder Award scheme to further explore the role of APEPTICO's compound 'Enaritide' for the treatment of Pseudohypoaldosteronism type 1b (PHA type 1b).

Based on its discovery work on interactions of the pulmonary epithelial sodium ion channel (ENaC) and various pharmacodynamically active protein structures, APEPTICO has been encouraged by the European Medicines Agency (EMA, London) to apply for a Pathfinder Award of the Wellcome Trust. The Wellcome Trust is an internationally leading charitable foundation dedicated to achieving extraordinary improvements in health by supporting the brightest minds. The Pathfinder Scheme offers pilot funding for discrete projects from partnerships between academia and industry to catalyse innovative early-stage applied research and development projects in areas of unmet medical need.

APEPTICO's Pathfinder Award "Effect of a synthetic peptide on PHA type 1b causing mutations in the amiloride-sensitive epithelial sodium channel (ENaC)" addresses the orphan disease Pseudohypoaldosteronism type 1b (PHA type 1b), a life-threatening condition in which the sodium ion channel, ENaC, found in kidneys, colon, lungs, salivary and sweat glands has either reduced or no functionality.

APEPTICO successfully develops various synthetic protein structures for treatment of various unmet pulmonary diseases. Since it was founded in 2009, APEPTICO has become a champion in pulmonary delivery of biologic macromolecules to patients with life-threatening lung diseases.

Bernhard Fischer, CEO of APEPTICO commented: "I am very proud that the Wellcome Trust has awarded the Pathfinder Grant to APEPTICO. Based on the funding scheme, we have initiated a scientific research collaboration with the Department of Pharmacology and Toxicology of the University Vienna." "In parallel with *in vitro* testing of the Enaritide-peptide in cells heterologously expressing human ENaC carrying mutations known to cause PHA type 1b, we will develop a specific dry powder formulation of the synthetic macromolecule, composed of micrometre small solid particles. This will enable APEPTICO to deliver the bioactive protein structure into the patient's lung via a dry powder inhaler" he added.

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To Editors

About the Wellcome Trust

The Wellcome Trust's vision is to achieve extraordinary improvements in human and animal health. In pursuit of this, the Wellcome Trust supports the brightest minds in biomedical research and the medical humanities. In 2013, the Wellcome Trust funded grants to more than 385 different organisations; more than 90 per cent of funding is awarded to organisations in the United Kingdom.

About APEPTICO GmbH

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About Pseudohypoaldosteronism type 1b

Pseudohypoaldosteronism type 1b (PHA type 1b) is a life-threatening condition in which the sodium ion channel, ENaC, found in kidneys, colon, lungs, salivary and sweat glands has either reduced or no functionality. Non-function of ENaC results in loss of sodium in the urine and faeces and severe salt imbalance in the body. Characteristic features are low levels of sodium (hyponatremia) and high levels of potassium (hyperkalemia) in the blood. The disease usually presents in newborns who fail to thrive and suffer from severe dehydration; other symptoms are abnormal heartbeat or shock due to salt imbalance and recurrent lung infections due to accumulated fluid. The condition does not improve with age and patients require life-long salt supplements and special treatment to remove potassium. If APEPTICO's synthetic protein structure activates the defective ENaC, then it could be used to treat lung ailments of PHA type 1b patients.

About the APEPTICO's synthetic protein structures

APEPTICO's molecules are synthetically manufactured structural equivalents to domains of the human Tumour Necrosis Factor α . The protein structures are water-soluble and can be administered into the lung by inhalation of liquid aerosol droplets of diameter 4 μm or less. Most recently, APEPTICO has successfully completed two phase II clinical trials with orally inhaled peptides for treatment of pulmonary permeability oedema and treatment of primary graft dysfunction following lung transplantation. APEPTICO's synthetic molecules have been granted orphan drug status various life-threatening condition by the European Medicines Agency (EMA) and by the Food and Drug Agency (FDA).

Contact

Univ.-Doz. Dr. Bernhard Fischer, Chief Executive Officer

APEPTICO Forschung und Entwicklung GmbH

Mariahilferstraße 136, Top 1.1.5

1150 Vienna, Austria

T: +43-664-1432919

F: +43-1-25330337795

E-mail: b.fischer@apeptico.com

URL: www.apeptico.com