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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Notes to Editors:

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™ and PEPSCREEN™ 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 a Phase IIa clinical study for the treatment of patients suffering from life-threatening oedematous respiratory failure.

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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