PRESS RELEASE

APEPTICO announces break-through scientific results for the use of solnatide for the treatment of High Altitude Pulmonary Oedema

Vienna, Austria, 15th November 2016: APEPTICO, a privately held biotechnology company developing peptide drugs, today announced that in collaboration with Professor Zhou Qiquan from the Medical University in Chongqing it has produced breakthrough scientific results for the use of solnatide for the treatment of High Altitude Pulmonary Oedema (HAPE).

In a complex animal study, conducted in climate chambers simulating ascent to a mountain altitude of 6,000 meters, and continuation of exposure of test animals for several days to both hypobaric and hypoxic high altitude conditions, it has been demonstrated that solnatide reduced pulmonary oedema, increased occludin expression and improved gas-blood barrier function during acute hypobaric hypoxia and exercise in rats (HAPE model). The breakthrough results for the use of solnatide for the treatment of High Altitude Pulmonary Oedema (HAPE) were recently published in the scientific journal Chest (November 2016: http://journal.publications.chestnet.org/article.aspx?articleid=2583274).

In the HAPE model used, the results provide convincing evidence that the anti-oedema and anti-inflammatory properties of solnatide render it more effective than currently used drugs, aminophylline and dexamethasone. Furthermore, solnatide used to treat HAPE, may exert an inhibitory effect on p38-MAPK signalling pathways, as well as inhibiting NLRP3 inflammasome activation, stabilizing the NF–kappa B pathway and reducing the synthesis of cytokines and the inflammatory response. In addition, solnatide can increase expression of the tight junction protein occludin, thereby improving the stability of the alveolar capillary membrane, improving impermeability and reducing leakage of protein into the alveolar fluid.

These results provide a rationale for the clinical application of solnatide to patients exposed to high altitude hypoxia environment and developing symptoms of High Altitude Pulmonary Oedema.

Commenting on the scientific results, Bernhard Fischer, CEO of APEPTICO, stated: “We are very excited about the excellent study results obtained by our Chinese collaboration partner Professor Zhou Qiquan from the Medical University in Chongqing. They show that solnatide is not only effective in activating lung oedema clearance in patients at normal altitude, but also has a significant potential to become the first emergency and interventional travel medicine for tourist and trekkers climbing to high altitude areas in Europe, Asia, America and Africa.”

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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. APEPTICO makes use of its technology platforms PEPBASE(TM) and PEPSCREEN(TM) to significantly reduce cost and to shorten time to market.

About solnatide

APEPTICO's proprietary therapeutic molecule solnatide (INN) is a synthetically manufactured structural equivalents to domains to a human proteins. solnatide is being developed by APEPTICO for the treatment of various forms of life-threatening pulmonary oedema. Liquid and dry powder formulations of solnatide can be administered into the lung by inhalation of aerosol particles with diameter 5 micrometres or less. solnatide activates the lung epithelial sodium channel (ENaC), located apically in alveolar epithelial cells, by directly binding to the crucial α-subunit of the channel, thus enhancing sodium ion uptake from the alveolar space across the alveolar cell membrane.

Solnatide has received orphan drug designation status for treatment of High Altitude Pulmonary Oedema by the European Commission and European Medicines Agency (EMA) and by the Food and Drug Agency (FDA).

About 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 6,000 meters, the standard barometric pressure is 47.2kPa (352 mmHg). At high altitude, the oxygen pressure falls below 50% of the sea level value. The reduced partial oxygen pressure in the atmosphere results in a drop of the alveolar and arterial oxygen pressure. 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.

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