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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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$^{(TM)}$ 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.

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