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PRESS RELEASE

Solnatide peptide expressed potent anti-inflammatory activity in joints

Vienna, 01st November 2022: In an antigen-induced arthritis model, solnatide peptide reduced cell influx and release of pro-inflammatory mediators into the joints, associated with reduction in oedema and tissue damage, as compared to controls indicating that the TNF-derived lectin-like solnatide peptide has anti-inflammatory effects in an acute model of joint inflammation, APEPTICO Forschung und Entwicklung GmbH today announced.

More recently, it was demonstrated that the solnatide peptide improves lung function in acutely inflamed lungs in both animal models of acute respiratory distress syndrome (ARDS) and in ARDS patients upon binding to the alpha subunit of the epithelial sodium channel (ENaC), which can be expressed in both epithelial and endothelial cells. Solnatide (a.k.a. TIP peptide, AP301) has also been shown to protect kidneys and to exert potent anti-inflammatory activity in an experimental glomerulonephritis model.

Scientists from the Universidade Federal do Ceará (Fortaleza, Brazil), the Universidade Federal de Minas Gerais (Belo Horizonte, Brazil), the Medical College of Georgia at Augusta University (Augusta, USA), the Friedrich-Alexander-University Erlangen-Nürnberg (Erlangen, Germany) and APETICO Forschung und Entwicklung GmbH (Vienna, Austria) investigated whether TNF-receptor-independent activities of TNF, such as those mediated by the TNF-derived solnatide peptide, which mimics the lectin-like domain, are protective in an immune-mediated arthritis mouse model.

The data published on 31st October 2022 in Frontiers in Immunology (https://doi.org/10.3389/fimmu.2022.1049368) for the first time demonstrate that solnatide significantly reduces inflammatory cell infiltration and joint damage in an immune-mediated experimental arthritis model in mice. The effect of solnatide was observed using both prophylactic and therapeutic strategies and following local (intra-articular) and systemic (intravenous) administration. Solnatide actions were also associated with a reduction in proinflammatory cytokine (IL-1b and IL-6) and chemokine (CCL2 and CXCL-1) levels in joint exudates.

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About APEPTICO

APEPTICO Forschung und Entwicklung GmbH ("APEPTICO") is a privately-held clinical stage biotechnology company with offices in Vienna, Austria, developing peptide-based products targeting life-threatening pulmonary diseases, including oedematous respiratory failure, acute lung injury, primary graft dysfunction, high altitude pulmonary oedema and PHA type 1. APEPTICO makes use of its technology platforms PEPBASE(TM) and PEPSCREEN(TM) to significantly reduce cost and shorten time to market.

About solnatide

APEPTICO's investigational compound *solnatide* (INN, laboratory code AP301) is a synthetically manufactured peptide, and was originally designed for the therapeutic treatment of patients with Acute Respiratory Distress Syndrome (ARDS) and various forms of life-threatening pulmonary permeability oedema (PPO). Orally inhaled solnatide IMP has completed a first-in-man (FIM) Phase I clinical study (EUDRACT No. 2011-000223-33), and has delivered clinical proof-of-concept in a randomised, placebo-controlled, double-blinded Phase II clinical study (EUDRACT No. 2012-001863-64) as well as in a Phase II pilot study (EUDRACT No. 2013-000716-21) in patients suffering from pneumonia, sepsis, ARDS, Primary Graft Dysfunction, and other causes of life-threatening pulmonary dysfunction. Currently, *solnatide* is being tested in a phase IIB clinical study for the treatment of life-threatening pulmonary permeability (EUDRACT No. 2017-003855-47), and is being used for the treatment of severe COVID-19 patients following infection with the new corona virus (SARS-CoV-2).

The crucial role of tumor necrosis factor (TNF) in joint destruction

In view of the crucial role of tumor necrosis factor (TNF) in joint destruction, TNF inhibitors, including neutralizing anti-TNF antibodies and soluble TNF receptor constructs, are commonly used therapeutics for the treatment of arthropathies like rheumatoid arthritis (RA). However, not all patients achieve remission; moreover, there is a risk of increased susceptibility to infection with these agents. Spatially distinct from its receptor binding sites, TNF harbors a lectin-like domain, which exerts unique functions that can be mimicked by the 17 residue solnatide peptide. This domain binds to specific oligosaccharides such as N′N′-diacetylchitobiose and directly target the alpha subunit of the epithelial sodium channel.