Press release: AdvanceCOR GmbH announces successful completion of preclinical development of thyroid stimulating hormone receptor (TSHR) peptide 19 for the treatment of patients with Graves´ disease and orbitopathy

Munich, February 2020

AdvanceCOR GmbH announces the successful completion of preclinical development of thyroid stimulating hormone receptor (TSHR) peptide 19 for the treatment of patients with Graves´ disease and orbitopathy.

Graves’ disease is one of the most common autoimmune diseases - the immune system mistakenly attacks the thyroid gland which becomes overactive. Symptoms in patients include an enlargement of the thyroid gland, swelling of the neck, skin changes, tremors, heat intolerance and sweating, significant weight loss, osteoporosis, cardiac arrhythmia such as atrial fibrillation and changes of the orbit (eye bulging). This impairment of eye function (“proptosis”) in Graves´ orbitopathy is especially hard to treat. The antibody-mediated autoimmune condition targets the TSHR, resulting in hyperthyroidism with an annual incidence of 15 – 80 per 100,000 persons throughout the world. Around 2% of all women will develop Graves’ disease during their lifetime. A quality of life (QOL) assessment showed that the disease is accompanied by a reduced vital and mental QOL for several years despite treatment according to current standards. If left untreated, Graves’ leads to significantly increased morbidity and mortality.

TSHR-derived peptide 19 interacts with immune mechanisms, induces tolerance and effectively treats Graves’ disease manifestations and orbitopathy in a long-term disease model, as recently published in the scientific journal “Thyroid” (Faßbender et al., Thyroid 2019; 29(2):258-267). Further preclinical investigations including a battery of high-dose safety tests have not revealed any safety issues, lack of immunogenicity, and favorable pharmacokinetic parameters. Submission of all documents (including investigator’s brochure and IMPD) to the European Medicine Agency’s (EMA) portal and BfArM has resulted in the confirmation that a first in man clinical trial is principally deemed possible by regulatory authorities, and can be started once final fill and finish of the existing good manufacturing practice (GMP)-compliant batch of TSHR peptide has been completed. This milestone corresponds to the US Food and Drug Administration’s investigational new drug (IND) status.

About AdvanceCOR GmbH
AdvanceCOR GmbH is a biotechnology company located in Martinsried near Munich, Germany. AdvanceCOR owns several clinical and preclinical projects generated from its own scientific program or from the university groups of the company’s founders.

For more information please contact
AdvanceCOR GmbH
Prof. Dr. Götz Münch
Fraunhoferstr. 9a
D-82152 Martinsried
Tel. ++49 (0)89 2000 204 10
Email: info@advancecor.com
www.advancecor.com