Value proposition/USP

A promising therapeutic concept is stem cell therapy. However, traditionally stem cells are difficult to produce, store and distribute for clinical use.

A means to effectively produce, store, distribute and administer adipose-derived mesenchymal stem/stromal cells (ASC) has been developed, and it has been shown in the clinic that these cells can be used in the treatment of ischemic heart diseases IHD.

IHD cause increasing morbidity in an ageing population, which is a huge burden for society. There is an unmet need for effective treatments for IHD to improve patient survival, quality of life and reduce health care costs. However, our products may be applied in several heart disease conditions and actually also in a wide range of malignancies where inflammation, and tissue regeneration may play a role.

Business Opportunity/Objective/Commercial Perspectives

Ischemic heart disease causes 40% of all deaths in EU and is the main cause of death in Europe. Overall cost for IHD in EU is almost € 196 billion a year – a cost expected to grow at a Compound Annual Growth Rate (CAGR) of 3.61\% during 2014-2020.

Conventional therapies have reduced IHD mortality significantly, but have left an increasing number of patients with chronic IHD and/or heart failure without further treatment options.

Stem cell products are being tested in heart diseases and in other indications, like prevention of transplant rejection, in diseases such as degenerative disc and joint disorders or inflammatory diseases.

The first stem cell products (approved in Japan) is indicated for treatment of radiation injury, chronic obstructive pulmonary disease, Crohn’s disease, GVHD, Type 1 diabetes and myocardial infarction.

Technology Description/Technology Summary

The technology developed enables production of ASC from donor abdominal adipose tissue. Cells are expanded in a closed bioreactor production system. Each production results within 4-6 weeks on average in approximately 50 treatment doses from each donor. Vials are frozen and shipped to treatment centres globally, where the product is administered by direct injection into the patients damaged heart tissue.

The product developed by the Cardiology Stem Cell Centre (CSCC) is easy to produce, store and transport – and this fully GMP grade product will advance dissemination and implementation of the therapy.

Development Phase/Current state

- An automated and scalable GMP production that is process fully compliant with EMA and FDA guidelines is developed.
- Clinical studies in patients with IHD have been conducted showing safety, applicability and clear effect indications
- Ongoing international multi centre clinical phase II studies will verify the clinical observations.

The Inventions

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Technology Seeking: Funding/Investors Licensee Partner/Research Collaboration IPR sale

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