Organization

Name of Organization / 会社名

Videregen Limited

URL

www.videregen.com

Brief Descriptions of Organization / 会社概要

Videregen is a clinical-stage regenerative medicine company using its proprietary stem cell-based technology platform to develop a range of personalised, non-immunogenic organ replacement products for orphan indications. Its lead programme is a tissue engineered trachea replacement, and its patented technology and know-how is also being applied to the development of other organ replacement products, including larynx, mucosal lining, small bowel and liver replacements. The platform technology, which uses decellularised organ scaffolds seeded with the patient's own cells to create new organs, has the potential to generate cost-effective and curative therapies for a range of devastating diseases.

Oral Presentation

Title of Presentation / 講演タイトル

Personalised, tissue engineered organ replacement

Abstract / 要旨

Videregen is a leader in the development of autologous tissue engineered products. Our leading programmes are focused on the development of orphan medicinal products for trachea, mucosal lining and larynx replacement. Clinical proof of concept and initial safety in man for the trachea replacement product have already been demonstrated in compassionate use cases.

The company's platform tissue purification technologies produce acellular biological scaffolds without significantly changing the natural three dimensional architecture of the extracellular matrix (ECM). The resulting acellular regenerative matrix retains the key topographical signals within the architecture and as all of the immunogenic epitopes have been removed from the processed organ tissues, they can be implanted into any patient without immune rejection. Therefore, the Videregen organ scaffolds can be regarded as universal donors, which by the addition of autologous cells from the patient, become personalised organ replacements.

GMP manufacturing processes are in place for the trachea and larynx products and we have an established supply chain for the production of the leading products for clinical trials and for commercial supply which is readily transferrable to additional territories.

UK MHRA and Ethics approvals are in place and formal Phase I clinical trials on the trachea and larynx replacement products are scheduled to start in the UK in H1 2017 and transition into pivotal Phase II trials in multiple centres in Europe thereafter.

Both the trachea and larynx and other organ replacement products are regulated in the EU as Advanced Therapy Medicinal Products (ATMP) and the tracheal product has recently been granted orphan medicinal product designation in the EU.

Objectives and/or Motives / 目的

Our objectives are to explore partnerships, collaborations and licensing opportunities in Japan to facilitate future market access. In parallel to our UK and EU clinical trials, we would like to initiate a Japanese trial, establish localised manufacture and collaborate for the further development of the R&D pipeline. Consequently we are interested in partnering with Japanese regenerative medicine or pharma companies with expertise in the following areas;

Regulatory pathways in Japan

- Clinical trials
  - Clinical trial for regulatory approval and market access in Japan
- GMP manufacture partner
  - Manufacture capability to service clinical trial and commercial supplies
- R&D pipeline development
  - Partners/ collaborators to accelerate pipeline development
- Market access