Horizon 2020 awards €6.8m to TETRA consortium for pivotal replacement trachea trial

EU study to build on Phase I trial of Videregen product & generate approval application

Liverpool, UK - December 10 2015: The pan-European TETRA consortium, led by Videregen Limited, has been awarded €6.8m under the Horizon 2020 programme¹ for a pivotal Phase II clinical trial of the company's tissue engineered replacement trachea. The project will start at the beginning of 2016 with the first patients to be treated in 2017, building on the results of the four-patient UK INSPIRE Phase I study². The study will focus on the orphan indication of severe structural airway disease (SSAD), a potentially life-threatening condition believed to affect around 12,000 people in Europe. The pivotal trial results are expected to lead to a European Marketing Authorisation application in 2019, with launch of the world's first commercially available tissue engineered organ replacement product in 2020.

The Phase II trial, which will recruit patients from five clinical sites across Europe, is to assess the safety and efficacy of the replacement trachea product. It will monitor how treatment reduces patients' need for additional interventions such as stents, as well as other factors such as impact on quality of life. The project also involves scale-out of stem cell manufacture from the UCL/Royal Free Hospital London Centre for Cell, Gene and Tissue Therapeutics to establish a second GMP manufacturing site in Munich, creating a pan-European supply chain. Validation of this production and supply system is an objective of the trial, as is demonstration of the product to patients and leading surgeons.

The 13-partner TETRA consortium brings together cross-disciplinary expertise in the areas of regenerative medicine, tracheal diseases and airway disorders, clinical trials and cell-based tissue engineered product manufacture. The principal investigator is Professor Martin Birchall (UCL, UCL Hospital NHS Foundation Trust) with additional trial sites at the University of Manchester/University Hospital of South Manchester NHS Foundation Trust (UK), Università degli studi di Brescia (Italy), Medical University of Vienna (Austria) and Instytut Gruzlicy i Chorob Pluc (Poland). Other parties include the Cell Therapy Catapult (pan-European regulatory processes and lead clinical research activities), TMC Pharma (regulatory affairs and lead clinical research activities), NHS Blood and Transplant (tissue retrieval and trachea scaffold manufacture), Klinikum Rechts der Isar der Technischen Universität München (stem cell processing and final product release) and Euram (project management).

Speaking for the consortium, Dr Steve Bloor, CEO of co-ordinator Videregen, said, ‘Award of this funding under the Horizon 2020 programme is fantastic news for the TETRA consortium, and a major step towards making our replacement trachea available commercially. With state-of-the-art manufacture facilities forming a European supply chain allied to leading clinical trial sites, we expect rapid recruitment of patients with this devastating disease which is associated with costs of €2.6bn pa in Europe. The results of the trial will also help expand Videregen's technology into other diseases and organ replacement products, and enhance the reputation of Europe in regenerative medicine. The TETRA consortium is very grateful for the support of Horizon 2020, and that of its stakeholders, funders and investors.’

Principal Investigator Professor Martin Birchall said, ‘We are delighted to be working on a project which will ultimately make the tissue engineered replacement trachea available on widespread basis to patients with SSAD. Designed to be a one-off curative treatment without
the need for a lifetime of anti-rejection drugs, it will bring real clinical benefit. Patients will be an important part of the wider TETRA project team, and we are grateful for the support of the National Association of Laryngectomee Clubs.'

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1 This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 681027

2 For more details of the INSPIRE trial please go to http://www.videregen.com/clinical-trial-for-replacement-trachea-technology-to-start-next-year/

3 Severe structural airway disease (SSAD) is associated with significant airway obstruction leading to high levels of morbidity and a 50% mortality rate if not treated successfully. Currently patients are subjected to repeated, limited efficacy, surgical interventions, such as stent insertions which ultimately have a high incidence of failure. In contrast, Videregen's tracheal replacement approach, which involves repopulating an acellular trachea ‘scaffold’ with the patient's own stem cells, is designed to be a one-off curative treatment without the need for a lifetime of anti-rejection drugs thereafter. The overall incidence of severe structural airway disease is estimated at c.11,8273 in EU per year. On average this patient group will spend 22 days in hospital at an average cost of €218,619 per patient translating to an EU-wide population cost of €2.6bn per year.

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About Videregen
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 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. The decellularisation technology was originally developed at Northwick Park Institute for Medical Research. Founded in 2011, Videregen is an SME based in Liverpool. Its investors include SPARK Impact, London Business Angels and others. For more information please go to www.videregen.com

About the Cell Therapy Catapult
The Cell Therapy Catapult was established in 2012 as an independent centre of excellence to advance the growth of the UK cell and gene therapy industry, by bridging the gap between scientific research and full-scale commercialisation. With more than 100 employees focusing on cell and gene therapy technologies, we work with our partners in academia and industry to ensure these life-changing therapies can be developed for use in health services throughout the world. We offer leading-edge capability, technology and innovation to enable companies to take products into clinical trials and provide clinical, process development, manufacturing, regulatory, health economics and market access expertise. We aim to make the UK the most compelling and logical choice for UK and international partners to develop and commercialise these advanced therapies. Regenerative medicine is one of the UK government’s eight great technologies that support UK science strengths and business capabilities. The Cell Therapy Catapult works with Innovate UK. For more information go to ct.catapult.org.uk or visit www.gov.uk/innovate-uk.
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About IGICHP (Instytut Gruzlicy I Chorob Pluc/National Institute of Tuberculosis and Lung Diseases)
IGICHP is a Poland-based pulmonary & respiratory research and clinical centre founded in 1877 in Warsaw. It has long-term experience in the research and implementation of new technologies and therapies with main focus on lung cancer, COPD, bronchial asthma and interstitial lung diseases. The Institute consists of 4 clinical and 7 diagnostic and research departments, and treats more than 11 000 inpatients and 30 000 outpatients annually. IGICHP is also the major teaching institution for respiratory medicine professionals in Poland. The Institute is the home for the national registries for lung cancer, alpha-1 antitrypsin deficiency and tuberculosis, as well as the lung cancer and multi-drug resistant Mycobacterium strains biobanks. For more information, visit www.igichp.edu.pl

About Medical University of Vienna
Medical University of Vienna (MedUni Vienna) is one of the most traditional medical education and research facilities in Europe. With almost 7,500 students, it is currently the largest medical training center in the German-speaking countries. With its 27 university hospitals and three clinical institutes, 12 medical theory centers and numerous highly specialized laboratories, it is also one of Europe’s leading research establishments in the biomedical sector.

About NHSBT
NHS Blood and Transplant (NHSBT) is a joint England and Wales Special Health Authority. Its remit includes the provision of a reliable, efficient supply of blood and associated services to the NHS in England and North Wales. It is also the organ donor organisation for the UK and is responsible for matching and allocating donated organs.

About Royal Free
The Royal Free attracts patients from across the country and beyond to its specialist services in liver, kidney and bone marrow transplantation, haemophilia, surgery for hepatopancreatobiliary (HPB) conditions, clinical neurosciences, renal, HIV, infectious diseases, plastic surgery, immunology, vascular surgery, cardiology, amyloidosis and scleroderma and is a member of the academic health science partnership UCLPartners. For further information, visit https://www.royalfree.nhs.uk/

About UCL (University College London)
UCL was founded in 1826. We were the first English university established after Oxford and Cambridge, the first to open up university education to those previously excluded from it, and the first to provide systematic teaching of law, architecture and medicine. We are among the world's top universities, as reflected by performance in a range of international rankings and tables. UCL currently has over 35,000 students from 150 countries and over 11,000 staff. Our annual income is more than £1 billion. www.ucl.ac.uk | Follow us on Twitter @uclnews | Watch our YouTube channel YouTube.com/UCLTV

About University Hospital of South Manchester NHS Foundation Trust (UHSM):
UHSM is a major acute teaching hospital trust providing services for adults and children at Wythenshawe Hospital and Withington Community Hospital and Community Services. We are recognised as a centre of clinical excellence in a number of specialist areas and provide district general hospital services and specialist tertiary services to our local community.

About UNIBS
The University of Brescia (UNIBS) is a public University which has chosen a common goal for all of its academic activities: the health and wellbeing of people and of the environment they live in. It is the first of its kind in Italy, and its “Health and Wealth” strategy is formally recognized by the Italian Ministry of Health. About two thirds of the UniBS Medical Faculty are associated with the Hospital in both clinical
and research activity. UNIBS consists of 8 departments, namely: Civil, Environmental, Architectural Engineering and Mathematics; Clinical and Experimental Sciences; Economics and Management; Information Engineering; Law; Mechanical and Industrial Engineering; Molecular and Translational Medicine; and Surgery, Radiology, and Public Health. There are currently 15,000 students enrolled, of whom 1,027 are foreign students.