

13 April 2015

AIM: RENE

ReNeuron Group plc
("ReNeuron" or "the Company")

ReNeuron files application to commence Phase I/II clinical trial in the US with its stem cell therapy candidate for the blindness-causing disease, retinitis pigmentosa

Guildford, UK, 13 April 2015: ReNeuron Group plc (AIM: RENE), a leading UK-based stem cell therapy company, today announces that it has filed an Investigational New Drug (IND) application with the US FDA to commence a Phase I/II clinical trial with its human Retinal Progenitor Cell (hRPC) therapy candidate for retinitis pigmentosa (RP). RP is a group of hereditary diseases of the eye that lead to progressive loss of sight due to cells in the retina becoming damaged and eventually dying.

ReNeuron has worked with world-leading collaborators and academic institutions in the retinal disease field to successfully take its retinitis pigmentosa programme through pre-clinical development. These include the Schepens Eye Research Institute/Massachusetts Eye and Ear (an affiliate of Harvard Medical School), UCL Institute of Ophthalmology, Moorfields Eye Hospital and the US-based Foundation Fighting Blindness, the world's leading private source of research funding for inherited retinal diseases. The pre-clinical programme has also benefited from UK Government funding under a BioMedical Catalyst grant, awarded in 2013.

Pre-clinical studies carried out in disease models by the Company's academic collaborators have demonstrated that, when transplanted into the retina, ReNeuron's retinal progenitor cell technology has the potential to preserve existing photoreceptors, potentially reducing or halting further deterioration of vision. In addition, the progenitor cells have been shown to mature into functional photoreceptors that engraft into the photoreceptor layer, bringing the possibility of restored vision.

The proposed Phase I/II clinical trial will be conducted at Massachusetts Eye and Ear, Boston, a world-renowned clinical centre for the treatment of retinal diseases. The trial design is an open-label, dose escalation study to evaluate the safety, tolerability and preliminary efficacy of the hRPC stem cell therapy candidate in up to 15 patients with advanced RP. The method of administration of the hRPCs will be a single sub-retinal injection. The primary endpoint of the study is safety, with patients being followed up for 12 months post-treatment with monitoring including measurements of visual acuity.

Subject to regulatory and local ethics approvals, ReNeuron expects to be able to commence the clinical trial in the second half of this year. ReNeuron's cell therapy candidate for RP has been granted Orphan Drug Designation in both Europe and the US by the European Commission and the FDA, respectively. Orphan Drug Designation is typically granted to drug programmes that potentially provide significant benefit to patients with rare diseases that are life-threatening or chronically debilitating. In acknowledgment of the relatively small patient populations involved, commercial and other incentives are provided to developers of orphan drugs.

Dr Eric Pierce, Director, Retinal Degenerations Service at Massachusetts Eye and Ear, and Principal Investigator for the clinical trial, commented:

“We are pleased to be working with ReNeuron on this important Phase I/II clinical trial. The human Retinal Progenitor Cells being tested in the study are promising since they can make photoreceptors. The implanted cells may not only prevent degeneration of patients' vision but may possibly restore some vision by replacing degenerated photoreceptor cells. The work leading to this clinical trial began over 15 years ago in the laboratory of Michael Young PhD, de Gunzburg Scholar and Co Director of the Ocular Regenerative Medicine Institute at the Schepens Eye Research Institute/Massachusetts Eye and Ear and Harvard Medical School.”

Olav Hellebø, Chief Executive Officer of ReNeuron, commented:

“We are delighted to have progressed our hRPC stem cell therapy candidate for RP to the point of submitting an application to conduct a clinical trial in the US. Once approved and commenced, the proposed Phase I/II clinical trial in RP patients will be the third clinical study ongoing with ReNeuron’s cell therapy candidates, alongside our Phase II clinical trial in stroke and our Phase I clinical trial in critical limb ischaemia. The proposed RP clinical trial initiates the Company’s clinical activities in the US, a very significant milestone in the development of ReNeuron as a global leader in the stem cell therapy field.”

Enquiries:

ReNeuron

+44 (0) 1483 302560

Olav Hellebø , Chief Executive Officer

Michael Hunt, Chief Financial Officer

Buchanan

+44 (0) 20 7466 5000

Mark Court, Sophie Cowles, Stephanie Watson

Cenkos Securities

+44 (0) 20 7397 8900

Stephen Keys, Dr Christopher Golden (NOMAD and Broker)

Russell Kerr (Sales)

About Retinitis Pigmentosa

Retinitis Pigmentosa (RP) is the name given to a group of inherited diseases of the retina that lead to a gradual and progressive reduction in vision and is the most common inherited cause of blindness in people between the ages of 20 and 60. The decline in vision is caused by the death of photoreceptor cells (both rods and cones) of the retina. Night blindness and difficulties with peripheral vision are the earliest and most frequent symptoms of RP, with reading and colour vision affected later. The age at which symptoms start is variable and the rate of deterioration of vision also varies from person to person. RP is typically diagnosed in adolescents and young adults and most sufferers will be legally blind by the age of 40. There are approximately 300,000 people living with RP in the US and Europe. There is currently no cure for RP and the main treatments currently used (high dose vitamins) slow the progression of RP in some patients, but also carry the risk of side effects.

About Massachusetts Eye And Ear

Founded in 1824, the Massachusetts Eye and Ear Infirmary has earned an international reputation for its successful treatment of the most difficult diseases and conditions of the eye, ear, nose, throat, head and neck, and for its outstanding contributions to medical research and education.

Mass. Eye and Ear clinicians and scientists are driven by a mission to find cures for blindness, deafness and diseases of the head and neck. After uniting with Schepens Eye Research Institute in 2011, Mass. Eye and Ear in Boston became the world's largest vision and hearing research center, offering hope and healing to patients everywhere through discovery and innovation. Mass. Eye and Ear is a Harvard Medical School teaching hospital and trains future medical leaders in ophthalmology and otolaryngology, through residency as well as clinical and research fellowships. Internationally acclaimed, Mass. Eye and Ear employs full-time, board-certified physicians who offer high-quality and affordable, specialty care that ranges from the routine to the very complex. U.S. News & World Report's "Best Hospitals Survey" has consistently ranked the Mass. Eye and Ear departments of ophthalmology and Otolaryngology as among the top five in the USA.

About ReNeuron

ReNeuron is a leading, clinical-stage cell therapy development business. Based in the UK, its primary objective is the development of novel cell-based therapies targeting areas of significant unmet or poorly met medical need.

ReNeuron has used its unique stem cell technologies to develop cell-based therapies for significant disease conditions where the cells can be readily administered "off-the-shelf" to any eligible patient without the need for additional immunosuppressive drug treatments. The Company's therapeutic candidates for stroke disability and critical limb ischaemia are already in clinical development and its cell-based treatment for the blindness causing disease, retinitis pigmentosa, is about to enter the clinic in the US.

ReNeuron is also advancing a proprietary platform technology to exploit nanoparticles (exosomes) secreted by stem cells as potential new drug candidates targeting a range of indications including cancer.

ReNeuron's shares are traded on the London AIM market under the symbol RENE.L. Further information on ReNeuron and its products can be found at www.reneuron.com.