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AIM: RENE

ReNeuron Group plc

ReNeuron announces first patient treated in US Phase I/II clinical trial in blindness-causing disease, retinitis pigmentosa

Marks initiation of ReNeuron's clinical development activities in the US

ReNeuron Group plc (the "Company") (AIM: RENE), a leading UK-based stem cell therapy development company, is pleased to announce that the first patient has been treated with the Company's cell therapy candidate for the blindness-causing disease retinitis pigmentosa (RP) in a first-in-human US clinical trial. The procedure, involving a single injection of hRPC cells under the retina, was conducted at Massachusetts Eye and Ear in Boston, a teaching affiliate of Harvard Medical School (HMS) and a world-renowned clinical and research centre for the treatment of eye disease, including retinal degeneration. The patient was discharged from hospital on the same day.

RP is a group of hereditary diseases of the eye that lead to progressive loss of sight due to photoreceptor cells in the retina becoming damaged and eventually dying. ReNeuron has demonstrated that its Human Retinal Progenitor Cells (hRPCs) improve visual acuity in pre-clinical models of retinal degeneration and, uniquely, the cells appear to both protect the host retina from further degeneration as well as engraft into the retina itself and differentiate into the photoreceptor cell types that are lost as a result of the disease. These putative mechanisms of action suggest that ReNeuron's cell therapy candidate could potentially treat any of the specific genetic variants of RP rather than, as is the case with gene therapy approaches, being restricted to the targeting of one particular genetic cause of disease.

The Phase I/II clinical trial is an open-label, dose escalation study to evaluate the safety, tolerability and preliminary efficacy of ReNeuron's hRPC cell therapy candidate in 15 patients with advanced RP. Importantly, the study marks the Company's initiation of clinical trial activities in the US.

The FDA has granted Fast Track designation to ReNeuron's hRPC programme targeting RP. This, together with the programme's Orphan Drug Designation in both the US and Europe, provides accelerated clinical development and marketing authorisation review processes for the RP therapeutic candidate as well as the potential for a significant period of market exclusivity once approved in these major territories.

Further patients have been identified for recruitment into the study and initial short-term safety and tolerability data from the Phase I part of the study are expected towards the end of 2016, with preliminary efficacy read-outs in the first half of 2017. Subject to the outcome of the Phase I/II study, the Company expects to be able to file an application in the second half of 2017 to commence a pivotal Phase II/III clinical trial with its cell therapy candidate for RP. A positive outcome from this pivotal study is expected to form the basis for subsequent marketing authorisation filings in both the US and Europe.

Eric Pierce, MD, PhD, Director of the Ocular Genomics Institute and Berman Gund Laboratory for Study of Retinal Degenerations at Mass. Eye and Ear and HMS and Principal Investigator for the clinical trial, commented:

“We are delighted to have treated the first patient in 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. We look forward to reporting future progress with this study in the months ahead.”

Joining Dr. Pierce as co-investigators are Dean Elliott, MD and Jason Comander, MD, PhD, both of Mass. Eye and Ear and the HMS Department of Ophthalmology.

Olav Hellebø, Chief Executive Officer of ReNeuron, said:

“The dosing of the first patient in the Phase I/II clinical trial of our cell therapy candidate for retinitis pigmentosa marks another significant milestone for ReNeuron. Retinal degenerative diseases represent extremely attractive targets for cell therapy approaches and our programme targeting RP benefits from a number of key competitive advantages in terms of the potential mechanisms of action of our hRPC cells and the potential speed of clinical development to market for this programme. With the start of this study, we are also delighted to have commenced clinical development activities in the US, a major target market.”

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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 the 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 become legally blind in later life. It is estimated that there are over 300,000 people living with RP in the US and Europe. There is currently no cure for RP and the main treatments used (high dose vitamins) slow the progression of RP in some patients, but also carry the risk of side effects.

About Mass Eye and Ear

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 company. 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 has therapeutic

candidates in clinical development for motor disability as a result of stroke, for critical limb ischaemia and for the blindness-causing disease, retinitis pigmentosa.

ReNeuron is also advancing its proprietary exosome technology platform as a potential new nanomedicine targeting cancer and as a potential delivery system for gene therapy treatments.

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.

This announcement contains forward-looking statements with respect to the financial condition, results of operations and business achievements/performance of ReNeuron and certain of the plans and objectives of management of ReNeuron with respect thereto. These statements may generally, but not always, be identified by the use of words such as "should", "expects", "estimates", "believes" or similar expressions. This announcement also contains forward-looking statements attributed to certain third parties relating to their estimates regarding the growth of markets and demand for products. By their nature, forward-looking statements involve risk and uncertainty because they reflect ReNeuron's current expectations and assumptions as to future events and circumstances that may not prove accurate. A number of factors could cause ReNeuron's actual financial condition, results of operations and business achievements/performance to differ materially from the estimates made or implied in such forward-looking statements and, accordingly, reliance should not be placed on such statements.