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Long term data from first clinical trial of ReNeuron's stem cell therapy for stroke to be presented at leading stroke conference

Long term data continue to show good safety profile and evidence of sustained improvements in neurological status and limb function

Guildford, UK, 17 April 2015: ReNeuron Group plc (the "Company") (AIM: RENE.L), a leading UK-based stem cell therapy company, today provides a further and final update on the PISCES Phase I clinical trial of its CTX stem cell therapy for disabled stroke patients.

Long term follow-up data out to at least 24 months in all patients treated in the PISCES study are being presented by the clinical team from Glasgow's Southern General Hospital on 19th April in a platform presentation at the 2015 European Stroke Organisation Conference (ESOC), taking place in Glasgow. The data are being presented ahead of submission for publication in a peer-reviewed clinical journal later this year.

There have been no cell-related or immunological adverse events reported in any of the eleven patients treated in the study (across the four ascending dose levels). Adverse events reported were related only to the implantation procedure or the patient's underlying medical condition.

Improvements in neurological status and limb function compared to pre-treatment baseline performance were observed within three months of treatment and maintained throughout long term follow-up. Improvements in the National Institutes of Health Stroke Scale (NIHSS) were seen in all dose groups. The NIHSS is a measure used to objectively quantify the impairment caused by a stroke. For all subjects, the median baseline score was 7. This improved to 5 at 3 months and was sustained at 2 years follow up with a median score of 5 ($p=0.002$).

Other measures of neuromuscular disability were supportive of the NIHSS improvement. Mean Ashworth Scale scores, a measure of limb spasticity, were 18.1 and 9.7 (affected upper and lower limb, respectively) at baseline, which improved to 15.7 and 7.8 at 3 months and 16.1 and 6.5 at 2 years. Improvements in scores on the Barthel Index (a measure of activities of daily living) were also consistent with the neuromuscular score changes with a median value of 12 at baseline, 14 at 3 months and 14 at 2 years.

The Company is currently conducting a UK multi-site Phase II clinical trial (PISCES II) to examine the efficacy of its CTX stem cell treatment in patients disabled by an ischaemic stroke. As a result of observed good safety profile of the treatment, the highest cell dose from the PISCES study is being used in the ongoing Phase II study. As with the PISCES study, the Phase II clinical trial involves a single, one-off injection of CTX cells into the brain. Subject to patient recruitment, initial data from this study are expected around the end of this year.

Olav Hellebø, Chief Executive Officer of ReNeuron, said:

"We are delighted to report long term data from all of the stroke patients treated in the PISCES study at this year's ESOC meeting. The data confirm the good safety profile of our CTX stem cell treatment

in this setting and it is particularly gratifying to see that the functional improvements previously observed in the patients against baseline measurements have been maintained in long term follow up. We look forward to reporting data from our ongoing Phase II study with CTX in disabled stroke patients in due course."

Professor Keith Muir, SINAPSE Professor of Clinical Imaging, Division of Clinical Neurosciences at the University of Glasgow, and Principal Investigator of the PISCES study, said:

"We continue to be both pleased and encouraged by the data from the PISCES study. The long term follow-up data continue to demonstrate the safety and tolerability of the CTX treatment. The evidence of functional improvement warrant further investigation and, in this regard, we are delighted to be a principal participating centre in the ongoing Phase II efficacy study with CTX."

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About the PISCES clinical trial

The PISCES study is the world's first fully regulated clinical trial of a neural stem cell therapy for disabled stroke patients. Stroke is the third largest cause of death and the single largest cause of adult disability in the developed world. The trial was conducted in Scotland at the Institute of Neurological Sciences, Southern General Hospital, Greater Glasgow and Clyde NHS Board.

The primary aim of the study was to test the safety and tolerability of the treatment in ascending doses of CTX cells, in patients with moderate to severe functional neurological impairments resulting from their stroke. The secondary aim of the study was to evaluate efficacy measures for the design of future clinical trials with CTX, including imaging measures as well as a number of tests of sensory, motor and cognitive functions.

About stroke

Approximately 150,000 people suffer a stroke in the UK each year and approximately 800,000 in the US. The vast majority of these strokes are ischaemic in nature, caused by a blockage of blood flow in the brain (as opposed to a haemorrhagic or bleeding stroke).

Approximately one half of all stroke survivors are left with permanent disabilities as a result of the damage caused to brain tissue arising from the stroke. The annual health and social costs of caring for these patients is estimated to be in excess of £5 billion in the UK and over $70 billion in the US, with stroke patients estimated to be occupying at least 25 per cent of long term hospital beds.

The only current treatment for ischaemic stroke patients occurs in the acute phase of the condition (within several hours of the stroke), when anti-clotting agents are administered to dissolve the clot causing the blockage in blood flow to the brain. Only a small proportion of patients get to the hospital in time to be treated in this way.

Beyond the acute phase, there are no existing treatments, other than preventative or rehabilitation measures, to alleviate the disabilities suffered by stroke patients who have survived their stroke.

Source: UK Stroke Association; American Stroke Association

About ReNeuron's CTX stem cell therapy for stroke

ReNeuron's CTX stem cell therapy for stroke consists of a neural stem cell line which has been generated using the Company's proprietary cell expansion and cell selection technologies and then taken through a full manufacturing scale-up and quality-testing process. As such, CTX is a cryopreserved, clinical and commercial-grade cell therapy product capable of treating all eligible patients presenting.

CTX has been shown to reverse the functional deficits associated with stroke disability when administered several weeks after the stroke event in relevant pre-clinical models of the condition. Extensive pre-clinical testing also indicates that the therapy is safe, in both acute and long term safety studies.

If ultimately shown to be safe and effective clinically, CTX would therefore offer a ground-breaking new treatment option for stroke survivors. The therapy offers the potential for a degree of recovery of function in disabled stroke patients, resulting in greater independence and quality of life for these patients and reduced reliance on health and social care systems.

The CTX cells that were used in the PISCES clinical trial are taken from the existing manufactured cell banks that will form the basis of the eventual marketed product. There will therefore be no need to re-derive and test new CTX cell lines for subsequent clinical trials or for the market – all such cells can simply be expanded from the existing banked and tested product.

About the Institute of Neurological Sciences at the University of Glasgow

The clinical Stroke Research Group of the Division of Clinical Neurosciences is based at the Institute of Neurological Sciences at the University of Glasgow and has major collaborations, internally with the Glasgow Experimental MRI Centre, with SINAPSE (Scottish Imaging Network: A Platform for Scientific Excellence), and with the Translational Medicine Research Initiative (TMRI). Around 900 patients per year are admitted through the Acute Stroke Unit, which provides stroke services to the population of south Glasgow and specialist stroke treatments for the West of Scotland.

The unit is the highest user of acute clot-busting (thrombolytic) treatment in the UK at present, and has been extensively involved in clinical trials in stroke. Major research interests include evaluation of advanced brain imaging techniques in acute stroke, development of novel brain imaging techniques, improving the use of clot-busting drug treatments in stroke, and developing trial methodology for evaluation of regenerative treatments. The group has support from the Stroke

Association, the Medical Research Council, and the TMRI. Further work with regenerative strategies include collaborations with groups developing both drug-based and stem cell therapies across Europe.

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.