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AIM: RENE

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

Positive stroke clinical data & regulatory update

Long term data from Phase II stroke clinical trial confirm positive results seen after three months

Results indicate that CTX cell therapy has potential to improve long term outcomes in disability, dependence and motor function in disabled stroke patients

ReNeuron Group plc (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, today provides an update regarding the Company's Phase II clinical trial (PISCES II) of its CTX cell therapy candidate for stroke disability and, in addition, an update regarding its global clinical and regulatory development strategy for the stroke programme.

The Company is pleased to announce that the positive response rates in key measures reported at three months after treatment in the PISCES II clinical trial were sustained at 12 months after treatment. PISCES II is a single arm, open-label study in patients living with significant disability resulting from ischaemic stroke. The Company announced positive initial data from the study in December 2016, when all patients had been followed up for at least three months after treatment.

At 12 months post-treatment, the response rates seen in the key measures of disability and dependency were maintained. The primary efficacy measure of the PISCES II study, motor function using the Action Research Arm Test (ARAT), improved between three and 12 months post-treatment. Importantly, the Modified Rankin Scale (mRS) response rate, a measure of disability and dependence, was maintained with 7 out of 20 patients (35%) showing a clinically relevant improvement. It is this measure of disability and dependence that is likely to be carried forward as a primary endpoint in future pivotal studies with CTX in this indication.

The PISCES II study also demonstrated that the CTX treatment was well tolerated in both short and longer term follow-up. Detailed safety and efficacy data from the study will be presented at a forthcoming medical conference.

These positive long term results are highly encouraging, indicating that the CTX therapy has the potential to produce meaningful and sustained improvements in disability as well as motor function in disabled stroke patients. No therapeutic

interventions are currently available to improve motor function and quality of life for disabled stroke patients, with physical rehabilitation measures being the current standard of care.

The Company will, as planned, shortly submit an Investigational New Drug application to the FDA to commence a randomised, placebo-controlled clinical trial in the US in disabled stroke patients. This study will involve fewer patients than the study originally planned with data expected to be available earlier, in the second half of 2019. The Company will continue its discussions with regulatory authorities worldwide but anticipates that a further pivotal study will likely be required for global marketing approval of the therapy.

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

“It is very encouraging to see that the improvements observed earlier in the PISCES II study have been maintained at the 12 month mark. As many patients live for the remainder of their lives with disability following a stroke, it is important that benefits from new treatments are maintained over the long term. In this regard, the safety and side effects of treatments are also important; we are pleased to see that the initial safety profile of CTX in this study has also not changed with longer term follow up. We look forward to the next phase of CTX development with investigation in randomised, placebo-controlled studies.”

Olav Hellebø, Chief Executive Officer of ReNeuron, said:

“We are delighted that the long term follow-up data from the PISCES II clinical trial has shown the potential of our CTX cell therapy candidate to permanently improve function in patients living with chronic consequences following stroke. Further, the study we plan to commence early in 2018 will allow critical placebo-controlled data with CTX in stroke disability to be available earlier than originally planned.”

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About the PISCES II clinical trial

The PISCES II clinical trial is a UK study of patients with motor disability as a result of ischaemic stroke. Eight centres across the UK's NHS hospital service were involved in recruiting and treating patients. A total of 23 patients were treated between two and thirteen months post-stroke, of which 20 have been followed up for at least 12 months. The patients were dosed with 20 million CTX cells which were injected by way of a routine surgical procedure into the putamen, the region of the brain involved in learning and coordinating movement. Patients were typically discharged home following a day of recovery in hospital. Patients in the study also received physiotherapy following their surgery. Arm and leg motor performance was tested in the study using Action Research Arm Test and Fugl-Meyer Assessment. Stroke severity and ability to carry out routine daily tasks were also measured, using the National Institutes of Health Stroke Scale, Modified Rankin Scale and Barthel Index. The PISCES II study was part-funded by a regenerative medicine and cell therapy development grant from Innovate UK, the UK's innovation agency.

About ReNeuron's CTX stem cell therapy candidate for stroke disability

ReNeuron's CTX stem cell therapy candidate for stroke disability 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 be safe and well-tolerated in an initial UK clinical trial (PISCES I) in eleven disabled stroke patients who were followed up for at least two years post-treatment. The data from this study were published in The Lancet. If ultimately shown to be safe and effective in larger, controlled clinical studies, 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 both the PISCES I and PISCES II clinical trials were 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 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 treatments for ischaemic stroke patients occur in the acute phase of the condition (within several hours of the stroke). During this phase, anti-clotting agents can be administered to dissolve the clot causing the blockage in blood flow to the brain or, alternatively, retrieval devices can be used to remove the clot and restore blood flow. Only a small proportion of patients are currently eligible 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

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 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 drugs that would otherwise be unable to reach their site of action.

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.

