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AIM: RENE

## RNS REACH

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

### **Phase II stroke data presented at AHA conference**

*Positive long-term data from Phase II stroke disability clinical trial accepted for a late-breaking podium presentation at the American Heart Association International Stroke Conference 2018*

ReNeuron Group plc (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to announce that positive long-term data from the Phase II clinical trial (PISCES II) of its CTX cell therapy candidate for stroke disability was accepted for a podium presentation given yesterday at the American Heart Association International Stroke Conference 2018 ("ISC 2018"), taking place this week in Los Angeles.

PISCES II is a single arm, open-label study in which a total of 23 patients living with significant disability resulting from ischaemic stroke were treated with ReNeuron's CTX cell therapy candidate. The Company recently announced positive top-line long-term data from the PISCES II clinical trial in which response rates in key measures reported at 3 months after CTX cell treatment were sustained at 12 months post-treatment.

Professor Keith Muir, SINAPSE Chair of Clinical Imaging, Clinical Director for Stroke, Queen Elizabeth University Hospital, Glasgow, and Principal Investigator for the PISCES II study, presented data at the conference showing upper limb functional recovery was durable and maintained out to 12 months post-treatment, with 30% of patients responding on the ARAT scale, a measure of upper limb mobility.

Data was also presented showing a response rate in 30% of subjects at 12 months post-treatment of at least a one point improvement on the modified Rankin Scale (mRS), a 7-point, clinician-reported global measure of disability or dependence upon others in carrying out activities of daily living. A one-point improvement in mRS is proven to be clinically meaningful for patients, both in terms of quality of life and healthcare resources needed to care for them. For example, improving from mRS 3 to 2 means that a person with a stroke regains their ability to live independently; perhaps returning home from a care facility, or enabling a spouse or carer to return to work.

Further, data analysis from a pre-specified subgroup of patients in the PISCES II study who had residual upper limb movement was presented, showing the appreciably higher response rate of 43% in these patients on the mRS. Patients similar to those in this subgroup, with moderate or moderate-to-severe disability (mRS of 3 or 4) and some remaining arm movement, will be the target population for the Company's upcoming PISCES III clinical trial with its CTX cell therapy candidate.

The data presented at the ISC 2018 conference indicate that the CTX therapy has the potential to produce meaningful and sustained improvements in the level of disability or dependence as well as motor function in disabled stroke patients. The PISCES II study also demonstrated that the CTX treatment was well-tolerated in both short and longer term follow-up.

ReNeuron recently announced that the FDA had given regulatory approval for the Company to commence a Phase IIb clinical study in the US with its CTX cell therapy candidate for stroke disability. The study, designated PISCES III, is a randomised, placebo-controlled clinical trial involving 110 patients across 25 clinical trial sites in the US. The primary end-point of the study will be a comparison of the proportion of patients in the treated and placebo arms showing a clinically important improvement on the mRS at 6 months post-treatment compared with baseline. Data from the study are expected in late 2019.

A copy of the ISC 2018 presentation will shortly be available on ReNeuron's website.

Further information about the conference may be found at:

[http://professional.heart.org/professional/EducationMeetings/MeetingsLiveCME/InternationalStrokeConference/UCM\\_316901\\_International-Stroke-Conference.jsp](http://professional.heart.org/professional/EducationMeetings/MeetingsLiveCME/InternationalStrokeConference/UCM_316901_International-Stroke-Conference.jsp)

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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](http://www.reneuron.com).

