24 January 2019 **AIM: RENE**

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

First patient treated in US stroke clinical trial

ReNeuron Group plc (AIM: RENE), a global leader in the development of cell-based therapeutics, is pleased to announce that the first patient has been treated in the US Phase IIb clinical study of the Company's CTX cell therapy candidate for stroke disability.

The study, designated PISCES III, is a randomised, placebo-controlled clinical trial involving 110 patients across 40 clinical trial sites in the US. Patients with stable post-stroke disability are entered into the study 6 to 12 months after their stroke and are randomised to receive either the CTX therapy or placebo treatment.

The primary end-point of the study is a comparison of the proportion of patients in the treated and placebo arms showing a clinically significant improvement on the Modified Rankin Scale, a measure of disability and dependence, at 6 months post-treatment compared with baseline. Top-line results from the study are expected in early 2020.

Further information on the PISCES III clinical trial can be found on the Company's website at www.reneuron.com and on the study's dedicated website at www.pisces3.org.

Sean I. Savitz MD, Professor and Director of the Institute for Stroke and Cerebrovascular Disease at the University of Texas Health Science Center at Houston (UTHealth), and Global Principal Investigator for the PISCES III study, commented:

"At McGovern Medical School at UTHealth, we have been studying cellular therapies as a novel treatment for stroke over the past 10 years. We are very excited to partner with ReNeuron and enrol the first patient into the PISCES III study. This study represents an important next step in the development of novel cellular therapies for chronic stroke and, to date, is the most advanced clinical trial to determine whether neural stem cells improve recovery in patients chronically disabled by stroke."

Olav Hellebø, Chief Executive Officer of ReNeuron, commented:

"We are delighted that the first subject has been treated in the PISCES III stroke clinical trial in the US with our CTX stem cell therapy candidate. No therapeutic

interventions are currently available to improve motor function and quality of life for disabled stroke patients. This important clinical trial moves us forward to potentially meeting this very significant unmet need."

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About ReNeuron's CTX cell therapy candidate for stroke disability

ReNeuron's CTX stem cell therapy candidate for stroke disability consists of neural stem cells which have been generated using the Company's proprietary cell expansion and cell selection technologies and then scaled up and manufactured under Good Manufacturing Practice (GMP) conditions. As such, CTX is a cryopreserved, clinical and commercial-grade cell therapy product capable of being provided at the time of use to patients at geographically diverse trial sites.

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[1]. A subsequent single arm UK Phase II study (PISCES II) showed clinically relevant improvements on key measures of disability and dependency out to 12 months post-treatment against a stable baseline level of disability in the 23 patients treated.

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 both the PISCES I and PISCES II clinical trials, as well as those to be used in the PISCES III study, 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.

1. *D.Kalladka, J.D.Sinden, K.Pollock, C.Haig, J.McLean, W.Smith, A.McConnachie, C.Santosh, P.M.Bath, L.Dunn, K.W.Muir. 2016. Human neural stem cells in patients with chronic ischaemic stroke (PISCES): a phase 1, first-in-man study. Lancet. 2016 Aug 20;388(10046):787-96*

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 and for the blindness-causing disease, retinitis pigmentosa.

ReNeuron is also advancing its proprietary exosome technology platform 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.

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.