14 December 2017 **AIM: RENE**

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

Stroke clinical trial regulatory approval in US

FDA approves ReNeuron's IND application to commence a Phase IIb clinical trial in the US in stroke disability

ReNeuron Group plc (AIM: RENE), a global leader in the development of cell-based therapeutics, is pleased to announce that the FDA has 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. Patients with stable post-stroke disability will be entered into the study 6 to 12 months after their stroke and will be randomised to receive either the CTX therapy or placebo treatment. 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 Modified Rankin Scale, a measure of disability and dependence, at 6 months post-treatment compared with baseline. Data from the study are expected in late 2019.

Olav Hellebø, Chief Executive Officer of ReNeuron, commented:

"We are delighted to have received regulatory approval to commence our first clinical trial in the US with our CTX cell therapy candidate for stroke disability. No therapeutic interventions are currently available to improve motor function and quality of life for disabled stroke patients. This important clinical trial represents a further step towards potentially meeting that very significant unmet need and we look forward to initiating the study during the first half of next year."

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About ReNeuron's CTX cell therapy candidate for stroke disability

ReNeuron's CTX 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. A subsequent single arm UK Phase II study (PISCES II) was recently completed, showing positive responses 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 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.