27 March 2014 **AIM: RENE**

ReNeuron receives UK regulatory approvals for Phase II clinical trial in stroke and Phase I clinical trial in critical limb ischaemia

Guildford, UK, 27 March 2014: ReNeuron Group plc (the "Company") (AIM: RENE.L), a leading UK-based stem cell therapy company, is pleased to announce that it has received final UK regulatory and ethical approvals to commence two new clinical trials, summarised below:

- Phase II clinical trial in stroke disability, recruiting up to 41 patients and treating 8-12 weeks post-stroke, regarded as the optimum treatment window for efficacy
- Second indication to enter the clinic – a Phase I clinical trial in critical limb ischaemia recruiting nine patients
- Both trials will use *CTXcryo,* the cryopreserved variant of ReNeuron's *CTX* cell line which provides the drug product for both the stroke and critical limb ischaemia programmes
- *CTXcryo* formulation has significant cost of goods, shelf life and ease-of-use benefits
- Early adoption of *CTXcryo* avoids the likely need for subsequent, time-consuming bridging studies, thereby accelerating time to market.

A multi-centre Phase II clinical trial will be undertaken at NHS hospital trusts throughout the UK with the Company's ReN001 investigational therapy for disabled stroke patients. The study will involve the treatment of up to 41 patients between 8 and 12 weeks after their stroke. Patients will be monitored on a number of validated stroke efficacy measures up to six months post-treatment. The treatment window in the Phase II clinical trial is regarded as optimum in terms of the potential efficacy of the ReN001 therapy and differs from the treatment window in the Phase I clinical trial with ReN001 where patients were treated at least 6 months after their stroke.

The Phase II study has been adopted by the NHS National Institute for Health Research Stroke Research Network (SRN), enabling the Company to work closely with the SRN to optimise performance against defined targets regarding site set-up, patient recruitment and monitoring activities across the various sites participating in the study. The study is expected to read out by the end of 2015.

Alongside the Phase II stroke study with ReN001, the Company has already commenced a non-interventional, observational study in stroke patients, initially at a selection of the clinical sites that will participate in the Phase II study. The observational study will allow for the pre-screening of potentially eligible patients for the Phase II clinical trial at the sites concerned, enabling such patients to be identified in good time while still in acute stroke care at the hospital. The observational study will also monitor eligible stroke patients who do not ultimately participate in the Phase II study with ReN001 on the same end-point measures, thus enabling a broad and valuable clinical data set to be built around the stroke patient sub-population targeted with the ReN001 therapy.

Separately, the Company has received final regulatory and ethical approvals to commence a Phase I clinical trial with its ReN009 investigational therapy for critical limb ischaemia (CLI). This major disease is common in patients with diabetes and can lead to amputation of the affected limb. The Company's ReN009 therapy is a cell-based treatment for CLI patients which, in pre-clinical studies, has shown the potential to restore sufficient blood flow in the affected lower limb to avoid amputation, and therefore the severe health consequences that typically result from such a procedure.

The Phase I clinical trial with ReN009 will be undertaken through NHS Tayside at Ninewells Hospital and Medical School, Dundee, Scotland. In this dose escalation safety study, the ReN009 cells will be administered via straightforward intramuscular injection into the affected lower limb of nine patients with peripheral arterial disease (CLI is the end-stage of this disease). Patients will be monitored for up to 12 months to assess the safety and tolerability of the treatment. Assuming Phase I patient recruitment runs to plan, and assuming a good short term safety profile for the ReN009 investigational therapy in the study at the highest dose, the Company expects to be able to file for approval to commence a Phase II efficacy study with ReN009, as planned, during the first half of 2015.

Importantly, both the Phase II clinical trial with ReN001 and the Phase I study with ReN009 will utilise a reformulated, cryopreserved variant of the Company's lead *CTX* stem cell line, designated *CTXcryo*. As previously announced, the Company has generated data demonstrating the equivalence of *CTXcryo* drug product to the original non-cryopreserved variant. These comparability data were recently submitted to the regulatory authorities as part of amended submissions for the above-mentioned Phase I and Phase II clinical trial applications.

The final regulatory approvals given for the studies will allow a significantly earlier than planned deployment of *CTXcryo* cells in clinical development, avoiding the need for bridging studies in the future and enabling ongoing clinical trial needs to be served much more efficiently and cost-effectively. The *CTXcryo* product variant will provide the business with major commercial and competitive advantages in terms of the availability of a genuine off-the-shelf cell-based treatment with a competitive cost of goods and a shelf life enabling shipping to, and storage at, clinical sites on a global basis.

Michael Hunt, Chief Executive Officer of ReNeuron, said:

"We are delighted to have received these concurrent clinical trial approvals for our stroke and critical limb ischaemia programmes. It is especially pleasing to have been given approval to use our second-generation *CTXcryo* cells in both of these new clinical trials. The fact that this new product variant is being deployed clinically much earlier than we had planned is illustrative of ReNeuron's ability, in collaboration with its various partners, to successfully innovate and sustain its commercial and competitive edge."

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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 in clinical development and its cell-based treatment for blindness-causing diseases of the retina is currently in pre-clinical development.

ReNeuron is also advancing a proprietary platform technology to exploit nanoparticles (exosomes) secreted by stem cells as potential new drug candidates targeting indications in tissue repair, fibrosis and 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.