



AIM: RENE

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ReNeuron Group plc

ReNeuron advances global clinical development strategy with cell therapy candidate for stroke disability

ReNeuron Group plc (the "Company") (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to provide an update on its CTX-based cell therapy development programmes.

In December 2016, we announced positive data from the Phase II clinical trial (PISCES II) of our CTX cell therapy candidate for stroke disability. PISCES II is a single arm, open-label study in patients living with disability resulting from ischaemic stroke. As a result of the positive data from this study, we are pursuing our plans to commence a randomised, placebo-controlled, Phase III clinical trial in the USA and Europe in patients who are living with disability post-stroke. As part of these preparations, we are conducting an End of Phase II meeting with the FDA later this month in order to seek further regulatory guidance prior to our submitting a formal application ("IND") to commence the US arm of the Phase III study. Subject to the feedback from this meeting, we plan to file the IND later this quarter with the aim of commencing the Phase III study in the second half of this year.

Separately, we have consulted with the European Medicines Agency on our plans for the Phase III stroke study. We have taken the advice received into account when developing our protocol for the study. In this regard, we intend to file a clinical trial application to regulatory authorities in Europe, shortly after the corresponding US submission.

Meetings with the Japanese regulatory agency ("PDMA") are also ongoing in order to advance our CTX cell therapy candidate for stroke disability in Japan under regulations that offer the potential for conditional marketing approval for cell therapies at an earlier stage of clinical development.

In order to focus on the significant opportunity presented by our stroke disability programme and our expanded retinal disease programmes (*see separate announcement issued this morning*), we have decided to put the programme for critical limb ischaemia on hold for the time being. Patient dosing was recently completed in a Phase I safety study in this indication, with no significant adverse safety events reported post-administration of the CTX cells via intramuscular injections.

Olav Hellebø, Chief Executive Officer of ReNeuron, said:

“There are currently no therapeutic interventions available to patients living with disability resulting from acute ischaemic stroke. We are therefore excited to be moving closer towards potentially changing this situation with our therapeutic candidate targeting stroke disability. After collecting further feedback from US and European regulatory authorities, we expect to be able to commence a Phase III study with our CTX cell therapy candidate in stroke disability in the second half of this year. We look forward to reporting further progress over the months ahead.”

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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 motor 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 gene therapy treatments.

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.