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AIM: RENE

ReNeuron Group plc

Stroke clinical data published in The Lancet

Published long term Phase I data show evidence of improvements in neurological function sustained out to 24 months and good safety profile

ReNeuron Group plc (the "Company") (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to announce the publication of long term follow up data from its PISCES I stroke clinical trial in The Lancet.

The PISCES I study was the first clinical trial of ReNeuron's CTX cell therapy candidate for patients with motor disability as a consequence of ischaemic stroke. The Lancet paper describes two-year follow up clinical data relating to the eleven stroke patients treated in the study.

The study was designed primarily to determine the safety of the CTX cell therapy candidate in patients with stable motor disability following their stroke. A number of secondary endpoints were also monitored to investigate possible signals of efficacy in the participants taking part in the study. Patients in the study were treated from twelve to fifty one months after stroke onset.

As previously reported at the 2015 European Stroke Conference, improvements in neurological status and limb function compared with pre-treatment baseline performance were observed within three months of treatment and maintained throughout long term follow up. Improvements in the National Institutes of Health Stroke Scale ("NIHSS") were seen in all dose groups. The NIHSS is a scale used to measure the neurological impairment caused by a stroke. For all subjects, the mean baseline score was 7.45. This improved to 5.09 at three months and was sustained at two years follow up with a mean score of 4.91 (p=0.002).

Improvements in other measures of neuromuscular disability were supportive of the NIHSS results. Ashworth Scale scores, a measure of limb spasticity, showed sustained improvement over the course of the two year study in both the affected arm and leg (mean improvement of 2.5 and 3.7 points). Scores on the Barthel Index, a measure of activities of daily living, also demonstrated improvement over the course of the study with a median improvement of 2 points at two years after treatment.

There were no cell-related or immunological adverse events reported in any of the patients treated in the PISCES I study across the four ascending dose levels.

The Lancet paper can be found at:

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)30513-X/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30513-X/abstract)

(Kalladka et al. The Lancet, 3 August 2016. [http://dx.doi.org/10.1016/S0140-6736\(16\)30513-X](http://dx.doi.org/10.1016/S0140-6736(16)30513-X))

ReNeuron recently reported that patient recruitment has completed into the ongoing Phase II clinical trial (PISCES II) of its CTX cell therapy candidate in stroke. The three month follow up data from this study are expected to be available in the fourth quarter of this year. The Company also reported that it has commenced formal interactions with regulatory authorities in Europe and the US regarding plans for a randomised, controlled, pivotal Phase II/III clinical trial with CTX in stroke disability. Subject to the results of the PISCES II study, the Company expects to file an application in the first quarter of 2017 to commence this pivotal Phase II/III clinical trial.

Professor Keith Muir, SINAPSE Professor of Clinical Imaging, Division of Clinical Neurosciences at the University of Glasgow, and Principal Investigator of the PISCES I study, said:

“The long term follow up data from the PISCES I study are both pleasing and encouraging. The data demonstrate the safety and tolerability of the CTX cell therapy treatment and the evidence of functional improvements have justified further investigation in the ongoing PISCES II efficacy study.”

Olav Hellebø, Chief Executive Officer of ReNeuron, said:

“We are delighted that the PISCES I clinical trial data has been published in such a prestigious peer reviewed medical journal as The Lancet. The data from this study have provided us with the impetus to move our CTX cell therapy candidate for stroke disability into the ongoing PISCES II clinical trial. We look forward to reporting the three month follow up data from this Phase II study later this year.”

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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.