

Green light for next stage of stem cell stroke trial

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The world's first clinical safety trial of a human neural stem cell therapy for stroke patients has been given the go-ahead to progress to its next stage.

The PISCES trial is being conducted by the University of Glasgow at the city's Southern General Hospital in partnership with pharmaceutical company ReNeuron.

The Phase I trial is looking at the safety of injecting expanded neural stem cells, in increasing doses, into the brains of a total of 12 patients left disabled by an ischaemic stroke, the most common form of the condition, and monitoring them over a period of two years.

The independent Data Safety Monitoring Board (DSMB) for the clinical trial has recommended the trial advances to the evaluation of a higher dose of [stem cells](#) in the third of four dose cohorts to be treated in the study.

In arriving at this recommendation, the DSMB reviewed safety data from the first two dose cohorts of six patients treated with ReNeuron's ReN001 stem cell therapy. Of these patients, two are through 18 month follow-up, one is through 12 month follow-up, one is through 9 month follow-up, one is through 6 month follow-up and one is through three month follow-up. No cell-related adverse events or adverse immune-related responses have been reported in any of the patients treated to date.

The trial team report that the first patient in this third dose cohort of three patients has now been successfully treated with ReN001 and discharged from hospital with no acute safety issues arising.

Professor Keith Muir, principal investigator in the trial, said: “We are very pleased that the trial is progressing well and that all the patients treated so far have shown no adverse effects.

“We are pleased to have successfully completed cell injection in the first patient at the new, higher, dose and remain encouraged by the results of the study thus far.”

The primary aim of the PISCES study is to test the safety and tolerability of the treatment in ascending doses of the ReN001 cells, in patients with moderate to severe functional neurological impairments resulting from their stroke. The secondary aim of the study is to evaluate efficacy measures for the design of future clinical [trials](#) with ReN001, including imaging measures as well as a number of tests of sensory, motor and cognitive functions.

In June of this year, interim data from the PISCES study from the first five patients treated was presented by the Glasgow clinical team at the 10th Annual Meeting of the International Society for Stem Cell Research (ISSCR) in Yokohama, Japan.

Reductions in neurological impairment and spasticity were observed in all five patients compared with their stable pre-treatment baseline performance and these improvements were sustained in longer term follow-up.

The PISCES study is the world’s first fully-regulated clinical trial of a neural stem cell therapy for disabled stroke patients. Stroke is the third largest cause of death and the single largest cause of adult disability in

the developed world. The trial is being conducted at the Institute of Neurological Sciences, Southern General Hospital, Greater Glasgow and Clyde NHS Board.

As announced recently, ReNeuron expects that, subject to a continuing lack of cell-related adverse events and affirmative Data Safety Monitoring Board advice, the remaining patients in the PISCES study will have been recruited and treated by early 2013, leaving the company on track to submit an application for a Phase II clinical study with ReN001 by mid-2013. These remaining [patients](#) have already been identified and evaluated as potentially eligible for treatment in the PISCES study, subject to further screening and consenting visits.

Michael Hunt, Chief Executive Officer of ReNeuron, said: “We are delighted that the DSMB have given a favourable recommendation to proceed to the higher and penultimate dose in the PISCES stroke trial. This represents a further important milestone for the study as we make our plans for a subsequent Phase II clinical trial application with ReNeuron’s ReN001 cell-based treatment for stroke disability.”

Provided by University of Glasgow

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