Encouraging data from stem cell trial in stroke patients as plans for Phase II progress

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Encouraging interim data from the world's first clinical trial examining the safety of neural stem cell treatment in stroke patients has been reported by researchers ahead of an application for Phase II trials.

Updated interim data from the PISCES trial, which has seen the brains of ischaemic stroke patients injected with neural stem cells to test the safety and tolerability of the treatment, was presented to the 22nd European Stroke Conference in London today.

Professor Keith Muir of the University of Glasgow, who is heading the trial of ReNeuron Group plc's ReN001 stem cell therapy at the Southern General Hospital, Glasgow reported that data from the first nine patients treated has shown no cell-related or immunological adverse affects.

He added that most patients had experienced sustained modest reductions in neurological impairment compared to their pre-treatment baseline performance, accompanied by improvement in abilities to undertake day to day tasks.

A further two patients have been treated since the data were collated and the trial is now drawing to a close, with full results due to be published next year.

Meanwhile, plans are proceeding for a Phase II trial which will examine the efficacy of stem cell treatment in stroke patients and an application is expected to be submitted to the UK regulatory authorities in early

July. If approved the Phase II trial is scheduled to commence later this year.

The Phase II trial will be a controlled multi-centre trial involving around 20 patients initially, all of whom will have suffered a stroke within a few weeks.

Professor Muir said: "We remain pleased and encouraged by the data emerging from the PISCES study. The data to date identify no safety issues with the ReN001 treatment – which is the primary focus of this Phase I trial.

"The evidence of functional improvement requires further investigation in a suitably designed Phase II efficacy study and we look forward to being a principal clinical site in that study when it commences."

Michael Hunt, Chief Executive Officer of ReNeuron, said: "The PISCES study continues to yield encouraging results. Assuming the remaining required short-term follow up data confirm the good safety profile of the treatment, we will be able to move the ReN001 therapy confidently into Phase II clinical development, as planned, later this year."

The Phase II study plan has been adopted by the NHS National Institute for Health Research Stroke Research Network (SRN). This important endorsement will enable ReNeuron 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.

ReNeuron will seek final regulatory and ethical approvals for the Phase II stroke study by submitting a data package including three month follow-up data on the final dose cohort in the PISCES study to the UK

[regulatory authorities](#) in early July and, assuming approvals are granted, expects to commence recruitment into the Phase II study shortly thereafter.

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.

Provided by University of Glasgow