Pioneering stroke stem cell study moves to next stage

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(Medical Xpress) -- A ground-breaking clinical study into the effects of a new stem cell therapy has received approval to progress to its next stage of development.

The PISCES (Pilot Investigation of Stem Cells in Stroke) study of ReNeuron Group plc's ReN001 therapy 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 therapy involves the introduction of neural stem cells into the brains of patients who have been affected by strokes with the aim of repairing damage and improving mental and physical function.

The study, which is being conducted at the Institute of Neurological Sciences in Glasgow's Southern General Hospital under the supervision of experts from the University of Glasgow, has been cleared by the national Data Safety Monitoring Board (DSMB) to advance to the next stage of evaluation, which will involve patients receiving a higher dose of ReN001.

The DSMB reviewed safety data from the first dose cohort of three patients treated with ReN001, each of whom who have been left disabled by an ischaemic stroke, the most common form of the condition. The first patient treated in the cohort was assessed at nine months post-treatment, the second patient at six months and the third

patient at three months. Laboratory safety tests, neurological examinations and neurofunctional tests conducted thus far indicate that the ReN001 treatment is safe and well-tolerated at the initial dose.

The Principal Investigator for the trial is Professor Keith Muir, SINAPSE Professor of Clinical Imaging, Centre for Stroke Research, Institute of Neuroscience & Psychology at the University of Glasgow.

Professor Muir said: "We are pleased that there have been no safety issues from the first dose cohort in the PISCES trial and we look forward to evaluating further patients at a higher dose. ReN001 has the potential to address a very significant unmet medical need in disabled stroke patients and I am pleased that our team is involved in this pioneering clinical trial."

The aim of the study is to test the safety and tolerability of the treatment in progressive doses while planning for the design of future clinical trials with ReN001, including structural and functional MRI imaging measures as well as a number of tests of sensory, motor and cognitive functions. In this Phase I single administration dose escalation study, the ReN001 stem cell therapy is being administered to a total of 12 stroke patients.

ReNeuron expects that the next dose cohort of three further patients will have been treated by the end of this year, assuming no significant recruitment delays. The remaining dose cohorts in the PISCES trial are expected to be treated in 2012, at which point ReNeuron intends to have discussed and agreed its subsequent clinical development strategy for ReN001 with the relevant regulatory authorities both in the UK and beyond. Patients in the clinical trial will be monitored for two years, with longer term follow-up procedures in place thereafter.

Michael Hunt, Chief Executive Officer of ReNeuron, added: "We are delighted that the DSMB have given a favourable recommendation to

proceed to a higher dose in the PISCES stroke trial. This represents an important milestone for the trial and the preliminary data from the trial also add value to our other therapeutic programmes using the CTX neural stem cell line that forms the basis of the ReN001 stroke treatment. We look forward to providing further updates on the PISCES clinical trial in due course."

Provided by University of Glasgow