

ReNeuron Group plc
 (“ReNeuron” or the “Company”)

Positive long-term data in retinal clinical trial

Meaningful clinical effect observed in patients out to 12 months post-treatment

Expansion of ongoing Phase 2a study includes plans to open a UK clinical site

ReNeuron Group plc (AIM: RENE), a global leader in the development of cell-based therapeutics, is pleased to announce positive long-term data from the ongoing Phase 1/2a clinical trial of its hRPC stem cell therapy candidate in retinitis pigmentosa (RP) and plans to expand the ongoing study. RP is a group of hereditary diseases of the eye that lead to progressive loss of sight and blindness.

In October 2019, positive interim efficacy data from patients treated in the Phase 2a segment of the ongoing Phase 1/2 study were announced by the Company and subsequently presented by Dr. Pravin Dugel at the American Academy of Ophthalmology Meeting in San Francisco. The data showed a group of subjects who had had a successful surgical procedure with sustained clinically relevant improvements in visual acuity compared with baseline, as measured by the number of letters read on the ETDRS chart (the standardised eye chart used to measure visual acuity in clinical trials).

Subsequent long-term efficacy data from the study continue to show a meaningful clinical effect from the therapy at all time points out to twelve months post-treatment. As previously reported, the degree of efficacy observed varies between patients, with mean results as set out in the table below:

Months post-treatment	Mean change from baseline in visual acuity in treated eye*	Mean change from baseline in visual acuity in untreated eye*	Difference in mean change between treated eye and untreated eye*
1	+11.4 letters (n=8)	+ 0.3 letters (n=8)	+ 11.1 letters (n=8)
2	+10.8 letters (n=8)	+ 1.6 letters (n=8)	+ 9.2 letters (n=8)
3	+14.0 letters (n=8)	+ 5.1 letters (n=8)	+ 8.9 letters (n=8)
6	+15.7 letters (n=6)	+ 6.5 letters (n=6)	+ 9.2 letters (n=6)
9	+16.5 letters (n=4)	+ 6.0 letters (n=4)	+ 10.5 letters (n=4)
12	+14.3 letters (n=3)	+ 7.0 letters (n=3)	+ 7.3 letters (n=3)

* In patients with a successful surgical procedure

The equivalent data set announced by the Company in October 2019 is as follows:

Months post-treatment	Mean change from baseline in visual acuity in treated eye*	Mean change from baseline in visual acuity in untreated eye*	Difference in mean change between treated eye and untreated eye*
1	+14.5 letters (n=6)	+1.5 letters (n=6)	+13.0 letters (n=6)
2	+13.0 letters (n=6)	+3.5 letters (n=6)	+9.5 letters (n=6)
3	+17.8 letters (n=6)	+8.3 letters (n=6)	+9.5 letters (n=6)
6	+28.7 letters (n=3)	+9.0 letters (n=3)	+19.7 letters (n=3)
9	+12.0 letters (n=1)	-1.0 letters (n=1)	+13.0 letters (n=1)

* In patients with a successful surgical procedure

The Company has submitted a protocol amendment to the US FDA to expand the Phase 1/2a study to treat up to a further nine patients in the Phase 2a segment of the study with a dose of two million hRPC cells, which compares with the dose of one million cells used in the study thus far. The amended clinical trial protocol also allows for a greater range of pre-treatment baseline visual acuity in patients and includes changes that enhance the ability to use microperimetry testing to measure and detect changes in retinal sensitivity in patients treated.

The Company and its clinical advisers believe that this protocol amendment will enable the efficacy signal observed in the study thus far to be both better delineated and magnified when demonstrated in a larger and more closely defined group of RP patients.

In addition, the Company has submitted an application to the MHRA to open the ongoing trial to a highly experienced UK clinical site, the Oxford Eye Hospital, with Professor Robert MacLaren, a world-renowned leader in the treatment of retinal diseases, as Principal Investigator.

The Company expects to present further data from the expanded Phase 1/2a clinical trial during the course of 2020 and expects to have sufficient data from the study to enable it to seek approval in the first half of 2021 to commence a pivotal clinical study with its hRPC cell therapy candidate in RP.

ReNeuron's clinical programme in RP has been granted Orphan Drug Designation in both Europe and the US, as well as Fast Track designation from the FDA in the US. Orphan Drug Designation provides the potential for a significant period of market exclusivity once the therapy is approved in those territories. Fast Track designation provides eligibility for an accelerated approval and priority review process by the FDA.

Olav Hellebø, Chief Executive Officer of ReNeuron, commented:

"We remain greatly encouraged by the data from the Phase 1/2a clinical study of our hRPC cell therapy candidate in patients with RP. The longer-term follow-up data are particularly noteworthy, demonstrating that the therapy appears to maintain its beneficial effects out to at least one year post-treatment."

ENDS

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About ReNeuron

ReNeuron is a global leader in cell-based therapeutics, harnessing its unique stem cell technologies to develop 'off the shelf' stem cell treatments, without the need for immunosuppressive drugs. The Company's lead clinical-stage candidates are in development for the blindness-causing disease, retinitis pigmentosa, and for disability as a result of stroke. ReNeuron is also advancing its proprietary exosome technology platform as a potential delivery system for drugs that would otherwise be unable to reach their site of action. ReNeuron's shares are traded on the London AIM market under the symbol RENE.L. For further information visit www.reneuron.com.