



15 January 2021

AIM: RENE

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

Clinical update

Treatment of first patient cohort completed in Phase 2a extension of retinal disease study

ReNeuron Group plc (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to provide an update on progress with the development of its hRPC (human retinal progenitor cell) therapy candidate for retinal diseases.

The hRPC therapeutic candidate is currently undergoing Phase 2a clinical evaluation for the treatment of the inherited blindness-causing disorder retinitis pigmentosa (RP). The study uses a cryopreserved hRPC formulation, enrolls subjects with advanced RP with some remaining central vision and, thus far, has been conducted at two clinical sites in the US.

The Company is pleased to report that dosing of the first cohort of three subjects in the Phase 2a extension segment of the study is now complete. This segment of the study is treating up to nine subjects with RP at a higher dose level than the first ten subjects already treated in the study. In line with the clinical trial protocol, the Data Safety Monitoring Board for the study will review short term safety data from this first cohort during the next few weeks, before the study proceeds to dosing the next cohort.

The Company has previously reported its intention to open the Phase 2a study up to new sites in the US and UK, having already received regulatory approvals to do so. The Company is pleased to report that the latest subject dosed in the study was treated at a new US site, the prestigious Casey Eye Institute, Oregon Health & Science University. The Principal Investigator at this new site is Mark Pennesi, MD, PhD, Associate Professor of Ophthalmology, Kenneth C. Swan Endowed Professor and Chief, Paul H. Casey Ophthalmic Genetics Division.

Dr Pennesi commented: “We are excited to enrol and treat our first patient in the study and have high hopes regarding the potential of this innovative new therapy for RP patients.”

As well as new sites targeted in the US and UK, an additional site in Spain is well progressed through the regulatory process. The Company expects to open the ongoing Phase 2a study to this site over the coming weeks.

Data from the extension segment of the Phase 2a study are expected to be presented later this year, once all remaining subjects have been treated. The Company anticipates that the expanded Phase 2a study will generate sufficient data to enable it to commence a single pivotal clinical study in the second half of 2022 with its hRPC cell therapy candidate in RP. The pivotal study will be designed to demonstrate further the safety and efficacy of this treatment

and, assuming a successful outcome, enable ReNeuron to seek marketing approvals for its hRPC cell therapy candidate in RP in selected major markets.

This programme 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 designated products may also be eligible for accelerated approval and priority review programmes offered by the FDA.

Olav Hellebø, Chief Executive Officer of ReNeuron, commented:

“We are extremely pleased to have completed dosing of the first subject cohort in the extended Phase 2a clinical study with our hRPC cell therapy candidate in RP patients. We are excited that one of the subjects was treated at a new clinical site in the US and we hope to add further new clinical sites shortly. The study continues to proceed according to plan.”

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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 cell therapy candidate is in clinical development for the blindness-causing disease, retinitis pigmentosa.

ReNeuron is also advancing its proprietary exosome technology platform as a potential delivery system for drugs that treat diseases of the brain. The Company also has the ability through its conditionally immortalised induced pluripotent stem cell (iPSC) platform to make

any tissue cells of choice; in-house programmes are focused on treatments for blood cancers and diabetes.

ReNeuron's shares are traded on the London AIM market under the symbol RENE.L. For further information visit www.reneuron.com