

6 September 2017

AIM: RENE

ReNeuron Group plc ("ReNeuron" or the "Company")

AGM Trading Update

ReNeuron Group plc (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to provide a trading update ahead of today's Annual General Meeting.

We are finalising the relevant data packages to enable us to submit an IND application to commence a pivotal Phase III clinical trial with our CTX cell therapy candidate for stroke disability in the US. We expect to make this submission, as planned, in the final quarter of this year, with the study expected to commence in early 2018, subject to the requisite regulatory approvals. We expect data from the Phase III study about two years later, in early 2020.

As previously reported, the FDA specifically recommended that we apply for a Special Protocol Assessment (SPA) for the proposed Phase III clinical trial. The SPA process is reserved for clinical studies considered pivotal in support of product marketing label claims. Further, we also plan to apply for Regenerative Medicine Advanced Therapy (RMAT) designation for our CTX cell therapy candidate for stroke disability. The benefits of RMAT designation are similar to those of Breakthrough Therapy designation, including increased interactions with the FDA during development and eligibility for priority review and accelerated marketing approval.

The ongoing US Phase I/II clinical trial of our human Retinal Progenitor Cell (hRPC) cell therapy candidate for retinitis pigmentosa (RP) is also proceeding well. We are pleased to report that all nine patients in the Phase I element of this study have now been treated, with short term safety and tolerability data expected in the final quarter of this year. The final high dose cohort of patients was treated with the newly developed cryopreserved formulation of our hRPC therapeutic candidate.

In order to garner the appropriate depth and quality of data to allow subsequent progression to a pivotal study in RP, we are currently finalising the relevant protocols to enlarge the Phase II clinical development plan in this indication. Based on this, we expect additional read-outs from the RP Phase I/II clinical trial in the second half of 2018, with further Phase II efficacy data from a larger cohort of patients expected in mid-2019. Further, we intend to file an application in the final quarter of this year to commence a Phase II clinical trial with our hRPC cell therapy candidate in patients with cone-rod dystrophy (CRD), to run concurrent

with the Phase II testing of this candidate in RP. CRD is a group of rare eye disorders associated with a loss of cone cells in the retina that initially results in deterioration of central visual acuity and colour vision. CRD frequently affects patients in childhood and has no cure. We expect Phase II efficacy data from the CRD programme in the second half of 2019.

Finally, in conjunction with our academic collaborators, we are continuing to generate pre-clinical data relating to our exosome development programme. Exosomes are nanoparticles secreted from cells including our proprietary CTX stem cell line. They play a key role in cell-to-cell signalling and early research with *ExoPrO*, our first CTX-derived exosome therapeutic candidate, has demonstrated that it may have a significant effect in regulating cell growth and apoptosis in cancer.

Over the past year, we have generated and presented important data relating to the characterisation, purification and *in vivo* biodistribution of *ExoPrO*, demonstrating its potential both as a novel therapeutic candidate and as a drug delivery vehicle. On the basis of the above progress and subject to continued success with ongoing pre-clinical development work, we hope to be able to commence clinical development with *ExoPrO* within the next year to 18 months, targeting solid tumours.

Olav Hellebø, Chief Executive Officer of ReNeuron, said:

"Our therapeutic development programmes continue to progress to plan, with further near term milestones in prospect as our stroke programme moves into Phase III clinical development and our retinal disease programmes move into Phase II clinical development. We look forward to reporting further progress with these programmes and our exosome development programme over the coming months."

Olav Hellebø will give a brief presentation at the AGM. The slides accompanying the presentation will be made available at the start of the AGM in the Investor section of the Company's website at <u>www.reneuron.com/investors/presentations</u>

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About ReNeuron

ReNeuron is a leading, clinical-stage cell therapy development company. Based in the UK, its primary objective is the development of novel cell-based therapies targeting areas of significant unmet or poorly met medical need.

ReNeuron has used its unique stem cell technologies to develop cell-based therapies for significant disease conditions where the cells can be readily administered "off-the-shelf" to any eligible patient without the need for additional immunosuppressive drug treatments. The Company has therapeutic candidates in clinical development for motor disability as a result of stroke, for critical limb ischaemia and for the blindness-causing disease, retinitis pigmentosa.

ReNeuron is also advancing its proprietary exosome technology platform as a potential new nanomedicine targeting cancer and as a potential delivery system for drugs that would otherwise lack adequate capacity to penetrate to their site of action.

ReNeuron's shares are traded on the London AIM market under the symbol RENE.L. Further information on ReNeuron and its products can be found at <u>www.reneuron.com</u>.

This announcement contains forward-looking statements with respect to the financial condition, results of operations and business achievements/performance of ReNeuron and certain of the plans and objectives of management of ReNeuron with respect thereto. These statements may generally, but not always, be identified by the use of words such as "should", "expects", "estimates", "believes" or similar expressions. This announcement also contains forward-looking statements attributed to certain third parties relating to their estimates regarding the growth of markets and demand for products. By their nature, forward-looking statements involve risk and uncertainty because they reflect ReNeuron's current expectations and assumptions as to future events and circumstances that may not prove accurate. A number of factors could cause ReNeuron's actual financial condition, results of operations and business achievements/performance to differ

materially from the estimates made or implied in such forward-looking statements and, accordingly, reliance should not be placed on such statements.