



**AIM: RENE**

**12 September 2018**

**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 pleased to announce that, following recent co-ordinating ethics committee approval, the first clinical site has been initiated in the US Phase IIb study with our CTX cell therapy candidate for stroke disability, with the first patient expected to be enrolled shortly. The study, designated PISCES III, is a randomised, placebo-controlled clinical trial in 110 patients.

The primary end-point of the PISCES III study is the proportion of patients in the treated and placebo arms showing a clinically important improvement on the modified Rankin Scale (mRS) at six months post-treatment compared with baseline. The mRS is a global measure of disability or dependence upon others in carrying out activities of daily living and is accepted by regulatory authorities as an appropriate end-point for marketing approval in stroke disability.

To date, over half of the planned 40 clinical sites have been approved for participation in the PISCES III study. Subject to meeting patient recruitment targets, the Company expects top-line data from the study slightly later than planned, in early 2020 (previously expected at the end of 2019). We expect the PISCES III study to be one of two pivotal studies required to support a marketing authorisation for the therapy in this indication.

A further announcement will be made when the first patient is treated in the PISCES III study.

On 11 July 2018, we announced the signing of an exclusivity agreement with a US-based specialty pharmaceutical company relating to the potential out-licensing of our hRPC retinal technology and therapeutic programmes. In exchange for granting a three-month exclusivity period, ReNeuron received a non-refundable \$2.5 million payment from the US-based company, with a further \$2.5 million payable to ReNeuron subject to the completion of certain ongoing due diligence activities during the exclusivity period. As previously reported, the Company aims to sign a definitive agreement with the third party concerned later this year, subject to agreement of final contractual terms.

As also announced in July, we are in active discussions with a number of third parties relating to our other platform technologies and programmes, with a view to potential collaboration and/or out-licensing deals in due course. These potential deals, if successfully concluded, will provide strong third party validation to our technologies and programmes as well as a source of significant non-dilutive funding to the Company.

In the preliminary results announcement in July 2018, we stated that we were working on a revised formulation of our hRPC drug product to optimise sub-retinal injection and subsequent disbursement of the hRPC cells, ahead of dosing of the remaining patients in the ongoing Phase I/II study with our hRPC cell therapy candidate in retinitis pigmentosa (RP). This study, which is being undertaken at Massachusetts Eye and Ear Infirmary in Boston, is an open-label, dose escalation study to evaluate the safety, tolerability and preliminary efficacy of our hRPC stem cell therapy candidate in patients with advanced RP.

We have now successfully developed an optimised formulation of the hRPC drug product for sub-retinal implantation and we are currently completing final comparability testing of this formulation prior to deploying it the Phase I/II study. As previously reported, we are also extending the study in order to expand the safety database in patients with less impaired vision than those treated thus far. Based on this, the Company expects short term read-outs from the Phase I/II study in mid-2019, with a Phase IIb study planned to commence shortly thereafter.

Pre-clinical development work continues with ExoPr0, our first CTX-derived exosome therapeutic candidate. Exosomes are nanoparticles secreted from cells including our proprietary CTX stem cell line. Exosomes play a key role in cell-to-cell signalling and early research with ExoPr0 has demonstrated its potential as both a novel therapeutic candidate and as a drug delivery vehicle.

We continue to build the pre-clinical data package for ExoPr0 and we have commenced discussions with regulatory authorities regarding the potential regulatory pathway to the clinic for ExoPr0. Subject to continued success with ongoing pre-clinical development work, we hope to be able to commence clinical development with ExoPr0 during 2019, targeting a solid tumour cancer indication.

**Olav Hellebø, Chief Executive Officer of ReNeuron, said:**

“Our therapeutic development programmes continue to progress to plan and we are particularly excited to have initiated the first clinical site in the US Phase IIb clinical trial with our CTX cell therapy candidate for stroke disability. We are also encouraged by the progress we are making in our partnering discussions. We hope to be able to conclude a definitive and substantial out-licensing agreement for our hRPC retinal stem cell technology later this year.”

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 [www.reneuron.com/investors/presentations](http://www.reneuron.com/investors/presentations)

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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 disability as a result of stroke 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 be unable to reach 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 [www.reneuron.com](http://www.reneuron.com).

*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.*