



26 March 2018

AIM: RENE

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

Product Development Update

ReNeuron Group plc (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to provide an update across its research and development programmes.

Highlights

- *CTX stem cell therapy candidate for stroke disability:*
 - *Increase in number of clinical sites planned for Phase IIb study*
 - *First patient treatment expected in mid-2018 leading to top-line data in late 2019*
- *hRPC stem cell therapy candidate for retinal diseases:*
 - *Four dose cohorts treated in ongoing Phase I/II study in retinitis pigmentosa*
 - *Phase I/II study to be expanded to target patients with less impaired vision ahead of future Phase IIb study*
 - *Top line Phase I/II data now expected in H1 2019*
- *Exosome nanomedicine platform:*
 - *Initial clinical trial application planned for 2019 in cancer*
- *Increasing collaborative work to exploit platforms beyond core therapeutic programmes*

CTX stem cell therapy candidate for stroke disability

We have continued our preparations to commence a Phase IIb clinical study in the US with our CTX cell therapy candidate for stroke disability. The study, designated PISCES III, is a randomised, placebo-controlled clinical trial in 110 patients. The primary end-point of the study will be a comparison of the proportion of patients in the treated and placebo arms showing a clinically important improvement on the modified Rankin Scale (mRS) at 6 months post-treatment compared with baseline. The mRS is a clinician-reported global measure of disability or dependence upon others in carrying out activities of daily living and is recognised by regulatory authorities as an acceptable end-point in late-stage clinical trials in stroke disability. As previously reported, 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.

We recently announced, on 26 January 2018, the presentation of positive long term data from the Phase II clinical trial (PISCES II) of our CTX cell therapy candidate for stroke disability at the American Heart Association International Stroke Conference 2018. The data presented at the conference indicate that our CTX therapy has the potential to produce meaningful and sustained improvements in the level of disability or dependence as well as motor function in disabled stroke patients.

We have taken the decision to increase the number of clinical sites in the PISCES III study from 25 to 40 in order to ensure that patient recruitment targets in the study are met. On this basis, and assuming the initial sites in the study are open for recruitment in the second quarter of this year following local ethics approvals, we expect first patient dosing in mid-2018 and top-line data from the study, as previously indicated, in late 2019.

hRPC stem cell therapy candidate for retinal diseases

Four cohorts of three patients each have been dosed in the ongoing US Phase I/II clinical trial of our hRPC cell therapy candidate for the blindness-causing inherited retinal disease, 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 now expect the hRPC therapy to be most effective in RP patients with a sufficiently intact retina to enable good engraftment of the hRPC cells and subsequent generation of functional photoreceptors. We are therefore extending the study in order to expand the safety database in patients with less impaired vision than those treated thus far. This is the patient group we will be targeting in a subsequent clinical trial in RP, which, as previously reported, will be a controlled Phase IIb study. The expanded Phase I/II study will also allow us to optimise the formulation and dosing of the hRPC therapy prior to commencement of the subsequent study.

Based on the above, we expect short term read-outs from the ongoing Phase I/II clinical trial later than originally planned, in the first half of 2019, with the Phase IIb study commencing shortly thereafter.

As previously announced, we intend to seek approval to commence a Phase II clinical trial with our hRPC cell therapy candidate in patients with cone-rod dystrophy (CRD) to begin shortly after the start of Phase IIb testing of this candidate in RP. CRD is a group of rare eye disorders associated with a loss of cone cells in the retina resulting in deterioration of central visual acuity and colour vision.

Exosome nanomedicine platform

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. They 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. Subject to continued success with ongoing pre-clinical development work, we hope to be able to commence clinical development with ExoPr0 during 2019, as previously indicated, targeting a solid tumour cancer indication.

Other activities

We are increasing the scope of our collaborative work with academic and commercial partners with the aim of exploiting the potential of our technology platforms beyond our core in-house therapeutic programmes.

In some cases, this collaborative work is being performed with the benefit of grant funding. An example of this was our recent announcement, on 13 February 2018, of the publication of new positive data with our CTX cell therapy candidate in a pre-clinical model of nerve injury, which demonstrated comparable nerve regeneration compared to standard of care treatment and a stronger muscle function response. The model, using our CTX cells as a component of artificial nerve tissue, was developed as part of a grant-funded collaboration with University College London and Sartorius Stedim Biotech.

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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 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 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.