

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

#### Strategic update

# Priority focus now on Exosome drug delivery technology & Partnerships Ophthalmology assets to be out-licensed

**ReNeuron Group plc (AIM: RENE),** a UK-based leader in Stem Cell and Exosomes Technologies, announces a strategic update following a review of the latest data from the hRPC (human retinal progenitor cells) Phase 2a clinical trial for retinitis pigmentosa (RP) and an assessment of the commercial potential for its Exosome technology.

Following a recent meeting of its Scientific Advisory Board in relation to the RP programme, and having considered the commercial implications for the Company, the ReNeuron Board has today taken the strategic decision to focus its research and development on its Exosome technology platform, where it currently has seven ongoing collaborations with further potential partnerships in discussion. Concurrently, the Company intends to out-license its RP programme assets following completion of the current clinical data package. A more detailed update on the RP clinical trial is provided further below.

The immediate cost savings will be re-directed towards an increased investment in the Exosome platform and provide a cash runway until late Q2 2023.

**Olav Hellebø, Chief Executive Officer, commented:** "While it is disappointing that the RP clinical data achieved so far has been inconclusive as to which patients respond best to our hRPC therapeutic candidate, we believe that the programme still offers promise. However, we believe this would be best further investigated by a partner. We are very excited about the market opportunity in Exosomes and importantly our tissue-for-tissue matching expertise that gives a truly differentiated offering to partners. We believe our work in this area offers the best returns for our shareholders and we are confident that we will increase the number of partners programmes this year and are already in the process of recruiting additional employees in this field."

**Iain Ross, Chairman of ReNeuron, added**: *"This has been a tough decision, but it is clear from the clinical data generated to date we cannot justify further substantial investment in the RP programme and that its future is better served in the hands of a third party. This decision allows us to increase our resource and investment in our Exosome technology platform and create increasing and sustainable shareholder value."* 

## Detailed update on Ophthalmology programme (hRPC Phase 2a trial)

The Company's RP study uses a cryopreserved hRPC formulation delivered via a subretinal injection. It enrols subjects with advanced RP with some remaining central vision. The study initially treated 10 patients with a 1 million cell administration (the "Initial Study") and was followed by an additional extension segment of the study proposing to dose up to nine patients with a higher level 2 million cell dose.

In the period to the end of December 2021 the Company can confirm that seven of the nine subjects in the extension arm have now been treated with the 2 million cell dose, with other potential subjects planned prior to year-end either unable to complete screening or found to be unsuitable upon screening. Although there have been no serious adverse events (SAEs) attributed to the drug itself, experience in treating the subjects at the 2 million cell dose has shown that the surgical procedure required to deliver this higher dose (which involves a greater volume and therefore greater surgical complexity) has led to more surgical complications compared to that seen with the 1 million cell dose. The data collected for this patient population, which was impacted by the SAEs and difficulty in deploying the 2 million cell dose, have to date shown very limited evidence of efficacy and given the SAEs, a number of patients saw a reduction in visual acuity in the treated eye.

Additionally, while data from the Initial Study showed at 12 months a mean 9.9 letter improvement versus baseline in ETDRS letter score (the standardised eye chart used to measure visual acuity in clinical trials), analysis of the 24-

month data, while inconclusive, does appear to show that efficacy wanes after 12 months. Four out of nine patients still show a positive response versus baseline at month 24.

The Board has reviewed its commercial strategy and the financial resources needed to progress the RP programme. Even though certain patients did appear to benefit from the treatment (in particular in the first 12 months), further patients would need to be treated at the 1m dose to try to identify which sub-populations are most likely to lead to a higher and longer lasting response. To fully understand this the Company believes an additional phase 2 trial would be needed and the Board believes that the size of the additional investment required from ReNeuron into this programme would not be in the best interests of shareholders. The Board believes that it therefore would be better to complete a data package on the programme and look to out-license the programme to a third party.

## Focus on Exosome drug delivery technology

The Company's proprietary cell lines produce a panel of distinct tissue matched Exosome drug delivery candidate which have the potential to target a variety of indications and tissue types. Exosomes produced by the Company's proprietary stem cell lines or via its induced pluripotent stem cell (iPSC) platform can be manufactured through a scalable process and loaded with a wide variety of payloads, such as nucleic acids (including siRNA, mRNA and miRNA), proteins (such as Cas9, antibodies and peptides) as well as small molecules.

Positive pre-clinical data has already provided proof-of-concept that ReNeuron's novel Exosome drug delivery technology can effectively deliver therapeutic proteins to the specific region of the brain affected by several neurological diseases such as stroke, Parkinson's disease and Huntington's disease. These studies have shown that ReNeuron's Exosome technology offers higher stability, more targeted delivery, and an increase in potency, therefore potentially solving the delivery issues that can be experienced with therapeutic proteins, and the Board believes this will be of interest to major pharmaceutical companies to aid in the treatment of a variety of neurological diseases.

Having already seen strong progress with the Company's Exosome platform, ReNeuron is adding additional scientists in the next two months to focus on this growth area.

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## About ReNeuron

ReNeuron is a UK based Proprietary Stem Cell based Exosome Technologies company, harnessing its unique stem cell technologies to develop 'off the shelf' treatments for disease with significant unmet needs.

ReNeuron's stem cell derived proprietary Exosome Technology platform offers a delivery mechanism for a variety of payloads such as siRNA, mRNA, proteins, small molecules and genes. The Company has a growing number of partner collaborations with Global Pharma, Biotech and academic partners in this fast-expanding area of scientific and commercial interest. ReNeuron also has the ability through its conditionally immortalised induced pluripotent stem cell (iPSC) platform to make allogeneic tissue cells of choice and has the potential to produce exosomes with tissue specific targeting ability.

The Company also has a Phase 2 cell therapy candidate in retinitis pigmentosa which it plans to out-license and also has out-licensed its CTX programme in stroke disability to Fosun in China.

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

This announcement contains inside information. The person responsible for arranging for the release of this announcement on behalf of the Company is Catherine Isted, Chief Financial Officer.