17 June 2020 **AIM: RENE**

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

Regulatory approvals and programme update

ReNeuron Group plc (AIM: RENE), a global leader in the development of cell-based therapeutics, provides the following update on its cell-based therapy programmes.

On 24 February 2020, the Company announced that it had submitted a protocol amendment to the US FDA to expand the ongoing Phase 2a clinical study of its hRPC stem cell therapy candidate in retinitis pigmentosa (RP) to treat patients at a higher dose level. This will enable the treatment of up to a further nine patients in the Phase 2a extension segment of the study (beyond the ten Phase 2a patients already treated). The Company also announced at that time that it had submitted an application to the MHRA to open the ongoing study to a highly experienced UK clinical site, the Oxford Eye Hospital, with Professor Robert MacLaren, a world-renowned leader in the treatment of retinal diseases, as Principal Investigator. These regulatory submissions followed recent positive long term data from the study (as also announced on 24 February 2020).

The Company is pleased to announce that it has received regulatory approval from both the FDA and MHRA for the expanded Phase 2a study in RP patients. The Company expects to commence treating patients shortly in both the US and the UK under the revised approved study protocol, subject to a continued easing of COVID-19 related restrictions at the relevant clinical sites. On this basis, the Company expects to present further data from the expanded Phase 2a clinical trial during the next twelve months and expects to have sufficient data from the study to enable it to seek approval in the second half of 2021 to commence a single pivotal clinical study with its hRPC cell therapy candidate in RP.

Following a review of programme priorities and resource requirements, the Company's existing resources will be refocused on programmes and activities offering the greatest prospect of value generation in the near to medium term. The Company therefore intends to focus its resources on its retinal disease programme and its exosome and induced pluripotent stem cell (iPSC) research platforms.

The Company has previously announced commercial collaborations to explore the potential of its exosomes to deliver therapeutic agents to the brain. Further collaborations with pharmaceutical/biotech companies are anticipated to commence over the coming months. ReNeuron's exosomes have a natural ability to cross the blood brain barrier and can be readily modified to carry a range of cargos, including siRNA, mRNA, proteins, peptides and small molecules. In response to COVID-19, the Company has also developed a proprietary exosome displaying the SARS-CoV-2 spike protein with the objective of out-licencing it for the potential delivery of COVID-19 vaccines.

The Company's induced pluripotent stem cell (iPSC) platform enables the derivation of an unlimited variety of different stem cell populations that can be utilised as new cell-based therapeutic candidates or for the production of exosomes with specific tissue targeting, thus providing further scope for a wide range of industry partnerships.

The Company's stroke disability programme with its CTX cell therapy candidate will continue through regional partnerships. ReNeuron's exclusive licensing partner in China, Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. ("Fosun Pharma"), will develop the Company's CTX cell therapy candidate for stroke disability in the licensed territory (Greater China including Hong Kong, Macao and Taiwan) where the Company has the potential to benefit from future operational and regulatory milestones under this out-license agreement. Clinical trial applications have recently been filed by Fosun Pharma to open clinical sites in the licensed territory to build on the clinical data already generated in the US. Patient recruitment in the PISCES III Phase 2b study with CTX in stroke disability, which has been on hold due to COVID-19 related restrictions, will remain suspended in the US for the foreseeable future; clinical trial sites will be kept open and patients already treated will be followed up over time in line with the clinical trial protocol.

The Company's CTX cell therapy candidate will be made available for licensing in stroke disability outside China. Positive data from the PISCES II Phase 2a clinical trial of CTX in stroke disability were recently published in the Journal of Neurology, Neurosurgery, and Psychiatry, available via the following link: http://jnnp.bmj.com/cgi/content/full/jnnp-2019-322515

The CTX cell therapy candidate will also be available for licensing in other indications such as Huntington's disease, a progressive genetic brain disorder where recently published non-clinical data has demonstrated the potential of CTX cells to address the deficits associated with the disease. The data, published in the journal *Stem Cells*, are viewable at the following link: https://stemcellsjournals.onlinelibrary.wiley.com/doi/10.1002/stem.3191

Further details of the Company's exosome and iPSC programmes will be provided in the Company's preliminary results for the year ended 31 March 2020, which are expected to be announced by mid July 2020.

Olav Hellebø, Chief Executive Officer of ReNeuron, commented:

"We are delighted to have received regulatory approvals in both the US and the UK to pursue our expanded Phase 2a study with our hRPC cell therapy candidate in retinitis pigmentosa. We look forward to recruiting additional patients into the study shortly, subject to continuing easing of COVID-19 restrictions in these territories.

"Focusing our in-house activities on our retinal disease and exosome-based programmes provides the Company with significant near-term opportunities to deliver value-enhancing data and commercial partnerships."

ENDS

This announcement contains inside information. The person responsible for arranging for the release of this announcement on behalf of the Company is Olav Hellebø, Chief Executive Officer.

Contacts:

	+44 (0) 20 3819 8400
ReNeuron Olav Hellebø, Chief Executive Officer Michael Hunt, Chief Financial Officer	
Buchanan (UK Media/Investor Relations) Mark Court, Tilly Abraham	+44 (0) 20 7466 5000
Argot Partners (US Media/Investor Relations) Claudia Styslinger, David Rosen	+1 212 600 1902
Stifel Nicolaus Europe Limited (NOMAD and Joint Broker) Jonathan Senior, Stewart Wallace, Ben Maddison	+44 (0) 20 7710 7600
N+1 Singer (Joint Broker) Aubrey Powell, James Moat, Tom Salvesen	+44 (0) 20 7496 3000

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 clinical-stage candidates are in development for the blindness-causing disease, retinitis pigmentosa, and for disability as a result of stroke. ReNeuron is also advancing its proprietary exosome technology platform 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. For further information visit www.reneuron.com.