AIM: RENE **5 June 2017**

ReNeuron Group plc

ReNeuron progresses clinical and regulatory strategy for the US with stroke programme based on positive FDA regulatory feedback

ReNeuron to apply for Special Protocol Assessment and Regenerative Medicine Advanced Therapy designation as part of US Phase III clinical trial application in stroke disability

ReNeuron Group plc (the "Company") (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to provide a further update regarding its US clinical and regulatory development strategy for its CTX cell therapy candidate for stroke disability.

We are pleased to report that we received favourable feedback from the FDA at the End of Phase II meeting conducted in April regarding our stroke programme. This favourable feedback was confirmed in the full minutes of the meeting, which we have now received. The FDA responded positively to our proposals regarding the design and conduct of the proposed Phase III clinical trial with CTX in patients with disability post-stroke. Significantly, the FDA specifically recommended that we apply for a Special Protocol Assessment (SPA) for the Phase III study. The SPA process is exclusively reserved for studies considered potentially pivotal in support of product marketing label claims.

Based on the FDA's recommendation, we plan to apply for an SPA for our proposed Phase III clinical trial with CTX for stroke disability.

As part of our US regulatory strategy, 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.

We are now working to finalise the relevant data packages to enable us to submit both the SPA and RMAT designation applications within the broader IND application to commence a Phase III clinical trial with CTX for stroke disability in the US. We expect to make this combined submission in the final quarter of this year, with the study now expected to commence in early 2018, subject to the requisite regulatory approvals.

Olav Hellebø, Chief Executive Officer of ReNeuron, said:

"We are greatly encouraged by the feedback we have received from the FDA regarding our planned US pivotal Phase III clinical trial with our CTX cell therapy candidate for stroke disability, most especially the recommendation that we seek a Special Protocol Assessment for the study. We take this feedback as an endorsement of our proposed approach to this important clinical trial and further recognition of the very large unmet medical need represented by patients left with lasting disabilities following an ischaemic stroke."

ENDS

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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 gene therapy treatments.

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.