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AIM: RENE

## ReNeuron Group plc

### Patient recruitment completed in Phase II stroke clinical trial

ReNeuron Group plc (the "Company") (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, is pleased to provide an update on progress with its stroke programme.

The Company has completed patient recruitment in the Phase II clinical trial (PISCES II) of its CTX cell therapy candidate in patients with motor disability as a result of ischaemic stroke. The three-month follow-up data from this study are expected to be available in the fourth quarter of this year.

ReNeuron has commenced formal interactions with regulatory authorities regarding plans for a randomised, controlled, pivotal Phase II/III clinical trial with CTX in stroke disability. In particular, representatives from the Company recently attended a face-to-face pre-IND meeting with the US Food and Drug Administration (FDA) to discuss plans for conducting the study in the US. The Company is incorporating the advice received in this meeting into the design and planning of the pivotal study. Similar discussions are taking place with the equivalent European regulatory body, the European Medicines Agency (EMA). Subject to the results of the Phase II study, the Company expects to file an application in the first quarter of 2017 to commence a Phase II/III clinical trial.

ReNeuron is also pleased to announce that it has appointed local representatives to assist the Company in taking advantage of the recently enacted and favourable regulatory regime for cell therapy candidates in Japan. These new Japanese regulations offer the potential for conditional marketing approval for cell therapies at an earlier stage of clinical development than in the West. The Company intends to pursue discussions with the Japanese regulatory authorities over the coming months in order to advance its CTX cell therapy candidate for stroke disability in Japan under the new regulations.

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

“The completion of patient recruitment in the PISCES II study in stroke disability marks another important step in the clinical development of our CTX cell therapy candidate for this condition. We are making good progress in planning the Phase II/III study, which we expect to be an international controlled study with patient recruitment in both Europe and the US.”

## ENDS

### ENQUIRIES:

#### ReNeuron

+44 (0)20 3819 8400

Olav Hellebø , Chief Executive Officer

Michael Hunt, Chief Financial Officer

#### Buchanan

+44 (0) 20 7466 5000

Mark Court, Sophie Cowles, Stephanie Watson

#### Stifel Nicolaus Europe Limited

+44 (0) 20 7710 7600

Jonathan Senior, Stewart Wallace, Ben Maddison (NOMAD and Broker)

### 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](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*

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