

AIM: RENE 8 June 2016

# **ReNeuron Group plc**

# Retinitis pigmentosa Phase I/II clinical trial update and Notice of US Key Opinion Leader event

ReNeuron Group plc (the "Company") (AIM: RENE), a leading UK-based stem cell therapy development company, is pleased to provide an update on progress with the ongoing US Phase I/II dose escalation study of its human retinal progenitor cell (hRPC) therapy candidate in patients with advanced retinitis pigmentosa (RP).

The Company also gives notice of an upcoming key opinion leader event which is to take place in the US on 13 June 2016, focusing on its retinitis pigmentosa programme.

The Company is pleased to report that the third and last patient in the first dose cohort of the study is scheduled for treatment within the next week. The second patient in the study was recently treated following a positive Data Safety Monitoring Board review of one month follow-up data from the first patient treated in this cohort.

The Phase I/II clinical trial is evaluating the safety, tolerability and preliminary efficacy of ReNeuron's hRPC cell therapy candidate in RP patients. The study is being conducted at Massachusetts Eye and Ear in Boston, a teaching affiliate of Harvard Medical School (HMS). The Principal Investigator of the study is Dr. Eric Pierce, MD, PhD, Director of the Ocular Genomics Institute and Berman Gund Laboratory for Study of Retinal Degenerations at Massachusetts Eye and Ear and HMS.

Initial short-term safety and tolerability data from the Phase I part of the study in the first nine patients are expected in early 2017. Longer-term safety data, as well as efficacy read-outs from the Phase II part of the study in a further six patients, are expected in the second half of 2017. Subject to the outcome of the Phase I/II study, we expect to be able to file an application in late 2017 or early 2018 to commence a pivotal Phase II/III clinical trial of hRPC in RP. A positive outcome from this study is expected to form the basis for subsequent marketing authorisation filings in both the US and Europe.

ReNeuron is pleased to announce that it will host an investor meeting in New York on 13 June at 12pm Eastern Time (ET) at which key opinion leaders in retinal diseases will discuss the field in general as well as ReNeuron's programme for RP

specifically. For further details and to RSVP for attendance in person, please contact Matthew Beck from the Trout Group at <a href="mailto:mbeck@troutgroup.com">mbeck@troutgroup.com</a>. All interested parties may also join by webcast, accessible through ReNeuron's website at:

www.reneuron.com/news/events/

Questions should be submitted to Mr. Beck via email for answer during the Q&A.

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

"The upcoming completion of the first patient cohort in this Phase I/II dose escalation study of our hRPC cell therapy candidate in retinitis pigmentosa represents an important milestone in the first clinical trial ReNeuron has undertaken in the US. We look forward to seeing the remaining patients treated in the study and to reporting data from the Phase II part of the study during the course of next year."

#### **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.