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AIM: RENE

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

**FDA grants Fast Track designation to ReNeuron's retinitis pigmentosa cell therapy candidate**

**Guildford, UK, 22 May 2015:** ReNeuron Group plc (AIM: RENE), a leading UK-based stem cell therapy company, today announces that the US Food and Drug Administration (FDA) has granted Fast Track designation to ReNeuron's human Retinal Progenitor Cell (hRPC) therapy candidate for retinitis pigmentosa (RP). RP is a group of hereditary diseases of the eye that lead to progressive loss of sight due to cells in the retina becoming damaged and eventually dying.

The granting of Fast Track status follows the Company's announcement on 5 May 2015 that it had received regulatory approval from the FDA to commence a Phase I/II clinical trial in the US with its stem cell therapy candidate for RP.

Fast Track designation is an FDA programme intended to expedite the development and review of new drugs or biological products targeting unmet medical need where the diseases concerned are serious or life threatening. Developers of products with Fast Track designation benefit from more frequent interactions with the FDA during clinical development as well as the potential for priority review and an accelerated market approval process for the product if supported by appropriate clinical data.

ReNeuron's cell therapy candidate for RP has already been granted Orphan Drug Designation in both Europe and the US by the European Commission and the FDA, respectively. Products with Orphan Drug Designation benefit from potential market exclusivity post-approval for up to 7 years in the US and up to 10 years in Europe.

The Phase I/II clinical trial with ReNeuron's cell therapy candidate for RP will be conducted at Massachusetts Eye and Ear, Boston, a world-renowned clinical centre for the treatment of retinal diseases. The trial design is an open-label, dose escalation study to evaluate the safety, tolerability and preliminary efficacy of the hRPC stem cell therapy candidate in up to 15 patients with advanced RP. Preparations for the study have commenced and ReNeuron expects the study to begin in the second half of this year.

**Olav Hellebø, Chief Executive Officer of ReNeuron, commented:**

"The granting of Fast Track designation from the FDA for our hRPC stem cell therapy candidate for RP is a very significant positive development for the Company. In considering the pre-clinical data we have presented to them and granting the designation, the FDA has recognised the potential of this treatment candidate to address RP as a serious unmet medical need. This, together with the Orphan Drug Designation already granted for the programme in both the US and Europe, provides accelerated clinical development and marketing authorisation processes for our RP treatment candidate as well as the potential for a significant period of market exclusivity once approved in these major territories."

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**About Retinitis Pigmentosa**

Retinitis Pigmentosa (RP) is the name given to a group of inherited diseases of the retina that lead to a gradual and progressive reduction in vision and is the most common inherited cause of blindness in people between the ages of 20 and 60. The decline in vision is caused by the death of the photoreceptor cells (both rods and cones) of the retina. Night blindness and difficulties with peripheral vision are the earliest and most frequent symptoms of RP, with reading and colour vision affected later. The age at which symptoms start is variable and the rate of deterioration of vision also varies from person to person. RP is typically diagnosed in adolescents and young adults and most sufferers will be legally blind by the age of 40. There are approximately 300,000 people living with RP in the US and Europe. There is currently no cure for RP and the main treatments used (high dose vitamins) slow the progression of RP in some patients, but also carry the risk of side effects.

**About ReNeuron**

ReNeuron is a leading, clinical-stage cell therapy development business. 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's therapeutic candidates for stroke disability and critical limb ischaemia are already in clinical development and its cell-based treatment for the blindness causing disease, retinitis pigmentosa, is about to enter the clinic in the US.

ReNeuron is also advancing a proprietary platform technology to exploit nanoparticles (exosomes) secreted by stem cells as potential new drug candidates targeting a range of indications including cancer.

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).