



AIM: RENE

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ReNeuron Group plc

FDA approves cryopreserved formulation of ReNeuron's retinal stem cell therapy candidate

New formulation enables expansion of Company's ophthalmology programmes

ReNeuron Group plc (the "Company") (AIM: RENE), a UK-based global leader in the development of cell-based therapeutics, provides an update on its cell therapy development programmes targeting degenerative diseases of the retina.

We are delighted to report that the FDA has approved the cryopreserved formulation of our human retinal progenitor cell (hRPC) therapeutic candidate and that we have now started treating patients with this formulation in our ongoing US Phase I/II study clinical trial in retinitis pigmentosa (RP) patients.

The new proprietary formulation enables the hRP cells to be frozen for shipping and storage and easily thawed at the point of clinical use. This freeze-thaw modality provides a greatly enhanced shelf life for the product, lower prospective cost of goods and the capability to ship the cells for clinical and commercial application anywhere in the world.

The new hRPC formulation has also facilitated an expansion of ReNeuron's clinical programmes in ophthalmology. As previously announced, we will shortly file an application with the FDA to expand the Phase II element of the ongoing Phase I/II clinical trial in RP from six to 20 patients. The expanded study is designed to provide the depth and quality of data that, if positive, will allow subsequent progression to a Phase II/III pivotal study in this indication. We also intend to file an application to start a new US Phase II clinical trial later this year in patients with cone-rod dystrophy, to be conducted alongside the Phase II part of the ongoing RP clinical trial.

Olav Hellebø, Chief Executive Officer of ReNeuron, said:

"We are delighted that the FDA has approved the use of the cryopreserved formulation of our hRPC retinal cell therapy candidate in our ongoing clinical development programmes. This is a further significant milestone for ReNeuron, enabling an expansion of our clinical programmes in ophthalmology as well as providing ReNeuron with a significant commercial advantage in terms of prospective cost of goods and ease of use of a retinal disease therapy."

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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

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