



29 June 2020

AIM: RENE

**ReNeuron Group plc**  
(“ReNeuron” or the “Company”)

**Further positive data in retinal clinical trial**

*Further long-term data demonstrate continuing, clinically meaningful efficacy at all time-points measured out to 18 months post-treatment*

ReNeuron Group plc (AIM: RENE), a global leader in the development of cell-based therapeutics, is pleased to announce further positive long-term data from the ongoing Phase 2a clinical trial of its hRPC stem cell therapy candidate in retinitis pigmentosa (RP). RP is a group of hereditary diseases of the eye that lead to progressive loss of sight and ultimately blindness.

On 24 February 2020, positive interim efficacy data from patients treated in the Phase 2a study were announced by the Company. The data continued to show a meaningful clinical effect from the therapy at all time-points out to twelve months post-treatment, as measured by the number of letters read on the ETDRS chart (the standardised eye chart used to measure visual acuity in clinical trials).

Since those results were announced, further long-term data from the study have been gathered from patients at six, nine, twelve and now, for the first patient treated, eighteen months follow-up. The Company is pleased to report that the latest data continue to demonstrate the efficacy of the therapy, with a clinically meaningful benefit being observed at all time-points. These results are particularly encouraging as RP is characterised by inexorable progression to blindness, with no therapy currently available for the vast majority of patients.

The results announced on 24 February 2020 excluded two subjects who experienced sight loss as a result of complications arising from the surgical procedure. The Company is pleased to report that one of these two patients has now recovered their vision and is back to at least baseline at one year post treatment.

As previously reported, the degree of efficacy observed varies between patients, with the latest mean results set out in the tables below. The first table shows the latest data including the above-mentioned patient who has recovered to at least the baseline level of vision in the treated eye. The second table shows the latest data excluding both of the patients who originally experienced surgical complications, to provide a comparison against the data previously announced on 24 February 2020.

Months post-treatment	Mean change from baseline in visual acuity in treated eye*	Mean change from baseline in visual acuity in untreated eye*	Difference in mean change between treated eye and untreated eye*
1	<b>+7.9 letters</b> (n=9)	+0.2 (n=9)	+7.7 (n=9)
2	<b>+8.0 letters</b> (n=9)	+1.2 (n=9)	+6.8 (n=9)
3	<b>+10.8 letters</b> (n=9)	+4.4 (n=9)	+6.4 (n=9)
6	<b>+9.6 letters</b> (n=9)	+3.4 (n=9)	+6.2 (n=9)
9	<b>+7.1 letters</b> (n=8)	+1.2 (n=8)	+5.9 (n=8)
12	<b>+11.9 letters</b> (n=5)	+4.3 (n=5)	+7.6 (n=5)
18	<b>+17.0 letters</b> (n=1)	+1.0 (n=1)	+16.0 (n=1)

\* Excluding one patient who experienced surgical complications

Months post-treatment	Mean change from baseline in visual acuity in treated eye*	Mean change from baseline in visual acuity in untreated eye*	Difference in mean change between treated eye and untreated eye*
1	<b>+11.4 letters</b> (n=8)	+0.3 (n=8)	+11.1 (n=8)
2	<b>+10.8 letters</b> (n=8)	+1.6 (n=8)	+9.2 (n=8)
3	<b>+14.0 letters</b> (n=8)	+5.1 (n=8)	+8.9 (n=8)
6	<b>+12.3 letters</b> (n=8)	+3.4 (n=8)	+8.9 (n=8)
9	<b>+11.8 letters</b> (n=7)	+1.2 (n=7)	+10.6 (n=7)
12	<b>+13.4 letters</b> (n=4)	+4.6 (n=4)	+8.8 (n=4)
18	<b>+17.0 letters</b> (n=1)	+1.0 (n=1)	+16.0 (n=1)

\* Excluding both patients who originally experienced surgical complications

The equivalent data set announced by the Company on 24 February 2020 is as follows:

Months post-treatment	Mean change from baseline in visual acuity in treated eye*	Mean change from baseline in visual acuity in untreated eye*	Difference in mean change between treated eye and untreated eye*
1	<b>+11.4 letters</b> (n=8)	+0.3 (n=8)	+11.1 (n=8)
2	<b>+10.8 letters</b> (n=8)	+1.6 (n=8)	+9.2 (n=8)
3	<b>+14.0 letters</b> (n=8)	+5.1 (n=8)	+8.9 (n=8)
6	<b>+15.7 letters</b> (n=6)	+6.5 (n=6)	+9.2 (n=6)
9	<b>+16.5 letters</b> (n=4)	+6.0 (n=4)	+10.5 (n=4)
12	<b>+14.3 letters</b> (n=3)	+7.0 (n=3)	+7.3 (n=3)

\* Excluding both patients who originally experienced surgical complications

On 17 June 2020, the Company announced that it had received regulatory approval from both the FDA and MHRA to expand the ongoing Phase 2a clinical study to treat patients with RP at a higher dose level. These approvals will enable the treatment of up to a further nine patients in the Phase 2a extension segment of the study (beyond the ten Phase 2a patients already treated). The Company expects to commence treating patients shortly in both the US and the UK under the revised approved study protocol, subject to a continued easing of COVID-19 related restrictions at the relevant clinical sites.

On this basis, and as announced on 17 June, the Company expects to present further data from the expanded Phase 2a clinical trial during the next twelve months and expects to have

sufficient data from the study to enable it to seek approval in the second half of 2021 to commence a single pivotal clinical study with its hRPC cell therapy candidate in RP.

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

“The latest longer-term follow-up data from our Phase 2a study of our hRPC cell therapy candidate in patients with RP continue to demonstrate a meaningful clinical benefit at all time-points, including in the first patient who has reached 18 months follow-up. The persistence of the observed clinical benefit is particularly encouraging. We look forward to announcing further data from the study in due course, as a prelude to taking our hRPC cell therapy into a pivotal, randomised study.”

**ENDS**

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**About ReNeuron**

ReNeuron is a global leader in cell-based therapeutics, harnessing its unique stem cell technologies to develop ‘off the shelf’ stem cell treatments, without the need for immunosuppressive drugs. The Company’s clinical-stage candidates are in development for the blindness-causing disease, retinitis pigmentosa, and for disability as a result of stroke.

ReNeuron is also advancing its proprietary exosome technology platform as a potential delivery system for drugs that treat diseases of the brain. The Company also has the ability through its conditionally immortalised induced pluripotent stem cell (iPSC) platform to make any tissue cells of choice; in-house programmes are focused on treatments for blood cancers and diabetes. ReNeuron’s shares are traded on the London AIM market under the symbol RENE.L. For further information visit [www.reneuron.com](http://www.reneuron.com).