ReNeuron Group plc

Now the dust has settled

19 November 2019

ReNeuron's clinical data presentation at last month's American Academy of Ophthalmology (AAO) meeting was met with some stock price weakness. The first 8 out of a total of 22 patients in the Phase I/IIa study included a 180-day update on the three patients initially reported in February where startling vision gains were reported. The first 12 patients in the Phase I study portion will now be followed for safety only. Two recently-dosed patients experienced some procedure-related vision loss. The results to date remain encouraging, while reminding us how early on the learning curve this technology is.

Ophthalmic data updated at AAO

ReNeuron's February announcement of the results of the first, three-patient cohort in its Phase I/IIa clinical study of the human retinal progenitor cell (hRPC) therapy for retinitis pigmentosa (RP) showed **rapid and significant** visual acuity gains. In March, it announced that the review of this data by the drug safety monitoring board had enabled in the next three-patient cohort in the Phase II part of the study to be dosed, and next in September the dosing of the final cohort was reported to be underway.

The second cohort comprised patients with a greater baseline visual acuity (*i.e.* less severe, or have better vision at baseline). The data on three of these less severe RP patients at the 90-day time point showed lower visual acuity gains than the first three patients dosed and in addition, two other new patients experienced some procedure-related vision loss. There was some concern on the apparent lower level of activity, yet:

- This is early in the development of the hRPC product where the dose of cells, the practice of the surgical procedure and the level of disease in the patient group most likely to respond best to the therapy have all not yet been defined. Less than a handful of pharmaceuticals have performed better in Phase III than in early clinical stages (we can only think of two – Roche's *Avastin* and GlaxoSmithKline's *BenLysta*) because as the clinical programme progresses the diversity of patients treated and the standard deviation of their response increases. To this end, ReNeuron may have stumbled on the most severe patients as being those with the greatest visual acuity to gain, very early in their clinical programme.

- Procedure-related vision loss in ophthalmic procedures where a drug is injected into the retina at the back of the eye is not unknown, even in more commonly treated indications like age-related macular degeneration (AMD). Indeed, early in November, NASDAQ-listed Regenxbio's Phase IIb study of its gene therapy for AMD was put on clinical hold by the FDA because of adverse events related not to the gene therapy, but to the surgical delivery system.

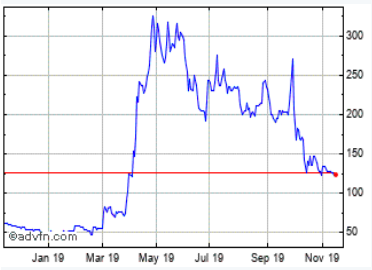
Conclusion: still early days

With results on only 8 of 22 patients presented so far, the data from this study needs to mature further. Longer-term (180-days of follow-up) read-outs in the first 3 (most severe) patients dosed continue to be encouraging.

Company Data

EPIC	RENE
Price	131p
52 week Hi/Lo	342p/29p
Market cap	£43m
Proforma cash Mar '19	£26.4m
Avg. daily volume	118,765

Share Price, p



Source: ADVFN

Description

ReNeuron Group plc is an AIM listed biotechnology company developing allogeneic cell therapies. Its first product is the CTX neural stem cell therapy for the treatment of chronic stroke disability with results expected in H1 2021. Its second product is human retinal progenitor cells (hRPCs) which are being studied for RP in a Phase I/IIa study.

Both of ReNeuron's clinical studies are being conducted in the US. ReNeuron's exosome platform is expected to be a source of technology licensing transactions.

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