ReNeuron
Changing Patients’ Lives

Ophthalmology Innovation Summit at AAO 2018

October 25, 2018

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ReNeuron Snapshot

Leading, clinical-stage stem cell company founded in 1997

Expertise in developing allogeneic cell-based therapies

Multiple assets targeting areas of significant unmet need

65 employees with facilities in the UK and Boston

London AIM market listing: RENE.L
ReNeuron Technology and Pipeline

**CTX platform:**
- Immortalised neural stem cell line
- 12 month shelf life
- Positive Ph IIa results in treated stroke survivors at 1 yr post

**hRPC platform:**
- Human retinal progenitor cell line
- Subretinal delivery
- Cryopreserved formulation extends shelf-life

**Exosomes platform:**
- Nano-sized particles from CTX cells
- Lead candidate has anti-cancer effects
- Potential as drug load/delivery vehicle

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Human Retinal Progenitor Cells (hRPC)
hRPC is a cell-based retinal therapy

**hRPC**: A unique and promising allogeneic cell-based therapeutic approach to retinal disease

1) Capable of differentiating into retinal cells and integrating into retinal layers

2) Broad therapeutic potential across range of retinal diseases

1. Long-standing collaboration with Schepens Eye Institute, Mass Eye and Ear, and University College London

2. Proprietary technology enabled development of GMP manufacturing process to support clinical application

3. Developed cryopreserved formulation to extend product’s shelf life allowing for worldwide shipment on demand

Initially targeting inherited retinal degenerative diseases
hRPCs preserves vision and integrate in retinal layers in established preclinical models

RCS dystrophic rats @ 12 weeks post-inj

Visual acuity (via OKR)

Allogeneic transplantation of pRPCs in pigs @ 4 weeks post-inj

Recoverin : photoreceptor marker; GFP: donor RPCs

Effects of hRPC associated with:
1) Differentiation into retinal cells;
2) Integration into host retina;
3) Trophic support of host cells
4) No immunosuppression required

Luo et al (2014)

hRPCs May Restore Lost Vision Associated with Inherited Retinal Disease (IRD)

**Retinitis Pigmentosa:** primary loss of rod photoreceptors.

>100 genes identified containing mutations leading to RP

**Cone Rod Dystrophy:** primary loss of cone photoreceptors.

>20 genes that can have mutations leading to this condition

Therapeutic benefit of hRPC approach not dependent on genetic causes of IRD

1https://www.genome.gov/13514348/learning-about-retinitis-pigmentosa/
2https://www.fightingblindness.ie/eye-conditions/cone-rod-dystrophies/
Retinitis Pigmentosa (RP)

• RP is an inherited, degenerative eye disease\textsuperscript{1,2,3}
  • Onset varies from early childhood to 20s/30s
  • Early stage main symptom is night blindness
  • Progressive loss of peripheral vision (ie tunnel)
  • Incidence of RP is 1:4000 in US and worldwide

• Orphan Drug Designation in EU and US

• FDA Fast Track Designation

There is no treatment for the vast majority of patients with RP

\textsuperscript{1}Hamel (2006) Orphanet J Rare Disease 1, 40;
\textsuperscript{2}https://nei.nih.gov/health/pigmentosa/pigmentosa_facts;
\textsuperscript{3}NORD
Phase I/IIa clinical trial (NCT02464436)
MEEI, Boston – J. Comander, E. Pierce (PIs)

Dose escalation study - Safety
250K, 500K, 1M cells (3 subjects per dose group)  Completed

Transition from fresh to cryopreserved formulation - Safety  Completed

Transition to “commercial” cryopreserved formulation – Safety then efficacy  Ongoing

- RP subjects with low VA have been treated to date
- Plan to shift into better seeing RP patients to assess efficacy
- DSMB has approved transition to “commercial” formulation at MTD
Analyst estimates of market potential for hRPC in RP*

Prevalence 1:4000 (worldwide) ~244K cases (US/EU/Japan)

Peak penetration 7.5% US/EU

Per-eye treatment cost

- €35K in EU
- $50K in US/Japan

Peak Annual Sales: $0.5 bn - $1.6 bn

*Stifel July 2016, N+1 Singer April 2017, Edison May 2017

Applicability of hRPC in other hard-to-treat ophthalmic diseases could provide upside potential
### Summary

**Industry-leading expertise in allogeneic stem-cell based therapies**  
*To target areas of significant unmet medical need*

**hRPC is promising therapeutic approach to retinal disease**  
*Potential associated with both protection of host cells and replacement of photoreceptors*

**GMP manufacturing process to support clinical application**  
*Produces “off-the-shelf” drug product available on demand*

**Cryopreserved formulation extends products shelf-life**  
*Commercial-ready cryopreserved formulation approved for clinical testing*

**Market potential for hRPC in RP is estimated to have peak annual sales in $0.5-1.6 billion range**  
*US/EU/Japan*