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A Leader in Cell-Based Therapeutics

- Leading clinical stage cell therapy company
  Sites in the UK and Boston, US
- Proprietary allogeneic stem cell technology platforms
- Two clinical stage therapeutic candidates targeting unmet medical needs
- Significant clinical validation milestones over the next 24 months
Proprietary Platform Technology

**hRPC**
- Human retinal progenitor stem cell line
- Cryopreserved formulation allows global ship-and-store
- Positive early Phase 2a data in retinitis pigmentosa
- Partnered with Fosun Pharma for China

**CTX Cells**
- Immortalised neural progenitor stem cell line
- 12 month shelf life (cryopreserved)
- Positive Phase 2a results in stroke disability
- Partnered with Fosun Pharma for China

**CTX-Derived Exosomes & iPS cells**
- High-yielding human neural stem cell-derived exosomes
- Proven ability to load exosomes with siRNA, miRNA and proteins
- Favourable distribution of exosomes across the Blood Brain Barrier
- Potential as drug load/delivery vehicle and as a therapeutic
- CTX-derived induced pluripotent stem cells (iPSCs) offer further licensing potential
<table>
<thead>
<tr>
<th>Programme</th>
<th>Indication</th>
<th>Pre-clinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Next Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>hRPC</td>
<td>Retinitis Pigmentosa</td>
<td></td>
<td></td>
<td></td>
<td>Further data read-outs from expanded Phase 2a study in 2020</td>
</tr>
<tr>
<td>CTX cells</td>
<td>Stroke Disability</td>
<td></td>
<td></td>
<td></td>
<td>PISCES III, pivotal, multi-centre U.S. Phase 2b study, data read-out expected mid-2021</td>
</tr>
</tbody>
</table>
Human Retinal Progenitor Cells (hRPC)
Human Retinal Progenitor Cells (hRPC)

hRPC: allogeneic cell-based therapeutic approach to retinal disease

- hRPCs differentiate into functional photoreceptors and integrate into retinal layers in pre-clinical models; integration may also enable durable trophic support
- Broad therapeutic potential across a range of retinal diseases
- Initially targeting inherited retinal degenerative diseases

Proprietary manufacturing process and controls allow for stable, high quality and high quantity GMP production

- Collaborations with Schepens Eye Research Institute and University College London
- Proprietary technology enabled development of GMP manufacturing process
- Cryopreserved formulation provides 9 month shelf life and enables local treatment worldwide
Retinitis Pigmentosa: An Unmet Need

- RP is an inherited, degenerative eye disease\(^1,2,3\)
  - Incidence of 1:4,000 in U.S. and worldwide
- >100 genes identified containing mutations leading to RP\(^4\)
- Orphan Drug Designation in EU and U.S.
- FDA Fast Track Designation

Therapeutic benefit of hRPC approach not dependent on genetic cause

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1. Hamel (2006) Orphanet J Rare Disease 1, 40;
3. NORD
Pre-clinical Studies Support RPC Potential in Degenerative Retinal Disease

**hRPC in RCS Dystrophic Rats 12 Weeks Post-Injection**

- hRPC Survival
- Vision (via OKR)

- hRPC (red)/photoreceptors (blue); white arrows indicate hRPC cells within retinal layers
- OKR = optokinetic response; OS = oculus sinister (left eye); OD = oculus dextrus (right eye)

- Evidence that hRPC:
  - Integrated into host retina
  - Provided trophic support of host cells
  - Preserved vision based on OKR

**pRPC in Pigs 4 Weeks Post-Injection**

- Transplanted donor cells (green); transplanted donor cells becoming photoreceptor cells (yellow) in the host retina (blue)
- IS = inner segments; ONL = outer nuclear layer; INL = inner nuclear layer

- Evidence that pRPC:
  - Differentiated into retinal cells
  - Integrated into host retina
  - Required no immunosuppression
# Pre-Clinical Data Support a Durable Response

<table>
<thead>
<tr>
<th>Species</th>
<th>Time after Treatment</th>
<th>Incidence of Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dystrophic RCS &amp; Normal Rats</td>
<td>28 weeks</td>
<td>77%; 23/30 dystrophic RCS rats</td>
</tr>
<tr>
<td></td>
<td></td>
<td>70%; 7/10 normal control rats</td>
</tr>
<tr>
<td>NIH-III Nude Mice</td>
<td>39 weeks</td>
<td>33%; 15/45</td>
</tr>
<tr>
<td>Mini Pigs</td>
<td>12 weeks</td>
<td>81%; 21/26</td>
</tr>
<tr>
<td>(allogeneic study mimicking the clinical scenario)</td>
<td></td>
<td>At 12 weeks a number of surviving pRPCs appeared to have migrated into the photoreceptor layer up to a depth of 2-3 layers, indicating cell integration.</td>
</tr>
</tbody>
</table>

**RPC cells survive for long periods in all species and survival is unaffected by the presence of disease**
Clinical Development – Phase 1/2a

Phase 1
- FIH, single ascending dose in subjects with established RP
  - Subjects with very poor visual potential
  - Four cohorts, three subjects each
  - Dose escalated to 1m cells
  - Formulation changed from fresh to cryopreserved cells
- Established safety in 1m cell dose in cryopreserved formulation

Phase 2a
- 6-12 additional subjects with established RP
  - Patients with better visual potential
    - 10 subjects treated
  - Primary endpoint: safety
  - Secondary measures: visual acuity, visual field, retinal sensitivity and retinal structure

U.S. Clinical Sites
- Massachusetts Eye & Ear Infirmary, Boston, Jason Comander, MD, PhD
- Retinal Research Institute, Phoenix, Pravin Dugel, MD
Phase 1/2a Recent Summary Results*

- Patient recruitment status:
  - 12 Phase 1 patients treated (>12 months follow up)
  - Phase 2a (ongoing)
    - 10 patients treated, follow up period:
      - 1 month: n=8; 3 months: n=6; 6 months: n=4; 9 months: n=1

- Good safety profile (n= 22):
  - No immune-related adverse events
  - No drug product related serious adverse events
  - 2 patients with surgical procedure related vision loss (one AE, one SAE):
    - Consistent with nature of sub-retinal injection procedure; one moderate and likely permanent, the other severe, but improving

- Clinically meaningful efficacy signals consistently seen:
  - Rapid and profound in some patients, more gradual in others

* American Academy of Ophthalmology Annual Meeting (AAO) in San Francisco – October 2019
## Phase 2a Recent Efficacy Results*

<table>
<thead>
<tr>
<th>Months post-treatment</th>
<th>Mean improvement in visual acuity in treated eye</th>
<th>Mean improvement in visual acuity in treated eye (excluding two patients with procedure-related vision loss)</th>
<th>Mean change in visual acuity in untreated eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>+8.3 letters (n=8)</td>
<td>+14.5 letters (n=6)</td>
<td>+1.6 letters (n=8)</td>
</tr>
<tr>
<td>2</td>
<td>+5.4 letters (n=8)</td>
<td>+13.0 letters (n=6)</td>
<td>+2.8 letters (n=8)</td>
</tr>
<tr>
<td>3</td>
<td>+6.1 letters (n=8)</td>
<td>+17.8 letters (n=6)</td>
<td>+6.8 letters (n=8)</td>
</tr>
<tr>
<td>6</td>
<td>+18.5 letters (n=4)</td>
<td>+28.7 letters (n=3)</td>
<td>+7.8 letters (n=4)</td>
</tr>
<tr>
<td>9</td>
<td>+12.0 letters (n=1)</td>
<td>+12.0 letters (n=1)</td>
<td>-1.0 letter (n=1)</td>
</tr>
</tbody>
</table>

*We’re excited by the progress of ReNeuron’s hRPC therapy. From the Foundation’s perspective, any gain in vision, or even stabilisation, is a major step forward for patients with RP as currently it is a condition where progressive loss of vision leads to blindness.*

Benjamin R. Yerxa PhD, Chief Executive Officer — Foundation Fighting Blindness (14 Oct 2019)
**Phase 2a Recent Efficacy Results**

ETDRS letters read: Phase IIa portion

*Mean changes in treated eye vs untreated eye*

<table>
<thead>
<tr>
<th>Mean change* (per timepoint)</th>
<th>+14.5 (n=6)</th>
<th>+13.0 (n=6)</th>
<th>+17.8 (n=6)</th>
<th>+28.7 (n=3)</th>
<th>+12.0 (n=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>treated eye</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>untreated eye</td>
<td>-1.0 (n=1)</td>
<td>+9.0 (n=3)</td>
<td>+19.7 (n=3)</td>
<td>+13.0 (n=1)</td>
<td></td>
</tr>
<tr>
<td>difference</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*excluding 2 patients with surgery-related vision loss*
hRPC Platform Next Steps

• Expand ongoing Phase 2a study to generate further and longer-term follow up efficacy data in a larger group of RP patients:
  • Potential modifications in patient selection and surgical strategy to enhance safety and amplify current efficacy signal
  • Subsequent potential single pre-approval clinical study, allowing shorter time to market

• Further top-line efficacy data from expanded Phase 2a study expected to be presented during 2020

• Assess other indications alongside RP (e.g. Cone Rod Dystrophy)
CTX Cell Therapy

CTX: allogeneic, cryopreserved, human neural stem cell product

- Promotes anatomical plasticity in the brain
- Excellent safety profile - no immunogenicity issues post-administration
- Manufactured under cGMP with a 12 month shelf life

Commercially Attractive

- Product can be easily ordered, shipped and stored at the hospital
- Delivered in cryo-shipper, controlled thawing at hospital site
- Administer to patient ‘on demand’
- Commercial scale manufacturing at attractive COGs
CTX Promotes Anatomical Plasticity in the Brain

Cells stereotaxically implanted in the putamen - modulate immune response to promote repair

Potential Mechanism(s) of Action

- Stimulate neurogenesis
- Stimulate/restore synaptic activity
- Stimulate angiogenesis
- Modulate inflammation
- Release of paracrine factors
- Cell trans-differentiation

Symptomatic relief of disability
Tissue restoration and/or repair

2 Sinden et al (2017) Stem Cells Dev 26, 1078-1085
CTX for Stroke Disability: Unmet Medical Need

- Stroke is the leading cause of morbidity and long-term disability in the U.S.\(^1\)
  - 1 in 6 people will have a stroke in their lifetime

- Financial burden
  - $34 billion annually in stroke-related costs in the U.S\(^1\)
  - Direct medical stroke-related costs projected to triple from 2012 to 2030\(^1\)

- Limited treatment options
  - Only one drug available, for use within 4.5 hours of stroke onset\(^2\)
  - Rehabilitation provides most benefit in first month, very little beyond six months\(^3\)

\(^1\)Benjamin et al (2017) Circulation 135, e146-e603;  
\(^3\)Hatem et al (2016) Front Hum Neurosci 10, 442
Severity of Functional Disability Measured by Modified Rankin Scale (mRS)

- mRS 5: Bedridden, requires constant help from others
- mRS 4: Needing help to walk, use toilet, bathe
- mRS 3: Can walk with appliance, needs some help at home
- mRS 0-2: Slight to no disability

Reductions in disability result in substantial reductions in patient care costs

Source: Company data; adapted from Lekander et al 2017, 42,114 patients from 2007-2012, costs from Sweden translated into $
**CTX in Stroke Disability: PISCES II Study Results**

**Phase 2a, single arm, open label study**

- 23 disabled, stable stroke patients, 2 to 12 mos post-stroke
- 20 MM CTX cell dose
- Clinically meaningful improvements in disability scales measured out to 12 months post-implantation
- No cell-related safety issues identified

**Very promising results for chronic stroke disability, supportive of a larger, randomised, placebo-controlled Phase 2b study**

<table>
<thead>
<tr>
<th>Time</th>
<th>Total subjects</th>
<th>Patients with NIHSS upper limb score &lt; 4 at baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month</td>
<td>N</td>
<td>Responders* (%)</td>
</tr>
<tr>
<td>Baseline</td>
<td>23</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>23</td>
<td>7 (30.4%)</td>
</tr>
<tr>
<td>6</td>
<td>22</td>
<td>6 (27.3%)</td>
</tr>
<tr>
<td>12</td>
<td>20</td>
<td>7 (35.0%)</td>
</tr>
</tbody>
</table>

*number of subjects with ≥ 1 point improvement in mRS (% of N observed at day of visit)

Greatest mRS improvements in subjects with residual movement of the affected arm (NIHSS UL <4)
PISCES III Study Design and Status

Phase 2b, Randomised, Placebo-Controlled Study

130 subjects - 2:1 randomisation to therapy v. placebo (sham) surgery
- Age 35-75 inclusive
- Ischemic stroke that includes supratentorial region (CT/MRI confirmed)
- 6-24 mos post-stroke
- mRS 3 and 4
- Some residual arm movement

Primary Endpoint*
- >1 pt improvement from baseline in mRS at 6 mos post-treatment

Secondary Endpoints* (1, 3, 6, 9, 12 mos post-tx)
- Barthel Index (ADL independence)
- Timed Up and Go test (lower limb and trunk function)
- Chedoke Arm/Hand Activity Inventory (upper limb function)
- NIHSS (impairment scale – neurological outcome and recovery)
- Fugl-Meyer Assessment (performance-based impairment index)
- EQ-5D-5L (QoL)

Current Status
- 12 surgical sites and 21 patient assessment sites now activated across US
- Clinical trial protocol amendments and other initiatives in place to enhance patient recruitment and enlarge data set for CTX-treated patients in study
- Top-line read-out expected in mid-2021
CTX-Derived Exosomes and iPS cells
CTX-Derived Exosomes: Biological Nanoparticles

- Nano-scale vesicles released by most cell types as a means of intercellular communication
- Naturally occurring liposomal delivery system
- Contain and transport bioactive lipids, proteins and nucleic acids

- First CTX-derived exosome candidate derived
- Potential as a drug delivery vehicle and as a therapeutic
ReNeuron’s CTX-Derived Exosome Technology

Advantages of ReNeuron’s exosome technology

- Stable, consistent, high-yield, clinical-grade product
- Fully qualified xeno-free, optimised, scalable GMP process
- Established analytics
- Proven ability to load miRNA and proteins
- Modifiable to carry siRNA/mRNA, CRISPR/Cas9 proteins, small-molecule inhibitors
- Favourable distribution across the blood brain barrier
- Engineered to target particular tissues

Advantages of exosomes as a delivery vehicle

- Natural carrier of nucleic acids and proteins, amenable for loading complex, hard-to-deliver therapeutic agents
- Ease of bioengineering
- Low immunogenicity
- Intrinsically durable, membrane texture order of magnitude harder than synthetic liposomes
CTX-derived induced pluripotent stem cells (iPSCs)

- OCT4, KLF4, SOX2, C-MYC

CTX cells can be rapidly and efficiently reprogrammed into a pluripotent state

- CTX-derived iPSCs retained immortalisation technology: key for consistency and scale up

- Potential:
  - New therapeutic candidates for subsequent out-licensing
  - Production of exosomes with tissue-specific targeting
Summary
Summary

- A global leader in cell-based therapeutics – sites in UK and Boston, US
- Allogeneic stem cell technology platforms – patented, scalable & cost effective
- Targeting diseases with large unmet medical needs
- Significant clinical milestones in retinal and stroke programmes in 2020 and 2021
- Near/medium term opportunities for value-generating partnering/collaboration deals