Spotlight on SF0166: topical eye droplet treatment for retinal diseases DME and wet-AMD
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Massive underserved retinal disease opportunity

>50m sufferers globally of retinal diseases leading to blindness, with incidence growing due to ageing population and diabetes explosion

Current treatments administered by monthly injections: high cost; significant patient discomfort; inconvenience
Retinal therapeutics generating enormous revenue

Two injectable drugs generate annual revenue >$8bn

| Indications                                                                 |  
|----------------------------------------------------------------------------|---
| • Neovascular (wet) Age-related Macular Degeneration (AMD)                   |   
| • Diabetic Macular Edema (DME)                                              |   
| • Macular Edema following Retinal Vein Occlusion                            |   
| • Diabetic Retinopathy (in patients with DME)                               |   
| US reimbursement ($ per injection)                                          |   
| $1,966 (2012)                                                               | $1,966 (2012) 
| Worldwide revenue (2016)                                                    |   
| $3.2 billion                                                                | $5.2 billion
| Worldwide revenue (2020F)                                                   |   
| $4.0 billion                                                                | $5.4 billion

Note: Lucentis and Eylea prescribed for DME, Wet-AMD and Retinal Vein Occlusion and Diabetic Retinopathy
Note: excludes Macugen (Wet-AMD only) and Bevacizumab (est. ~$2B)
Source: 2016 Annual reports for Roche, Novartis, and Regeneron and 2014 Global Data
Diverse approaches are being pursued to address retinal disease

**Challenges**

- **Ocular Injectables**
  - Monthly injections
  - Attempts to increase potency & reduce injection frequency

- **Topical eye droplet**
  - Historical challenges: other eye droplet candidates failed
    - Do not reach retina
    - Toxicity
    - Lack biological effect

- **Oral or systemic**
  - Can impact whole body
  - Retinal barrier
The Holy Grail of retinal disease is an eye droplet

SF0166 is radically differentiated

1. Route of administration: Self-administered


3. Clinical results
   - Excellent safety profile
   - Biological activity

4. Highly protected
   - 6 issued patents; protection to 2034
Clinical and scientific advisors

Leading ophthalmologists who ran Phase 3 trials for Lucentis and Eylea

Jeffery Heier, MD
- Ophthalmic Consultants of Boston
- Lead investigator for MARINA (Lucentis Phase 3)
- Chair Steering Committee for VIEW (Eylea Phase 3)

Peter Kaiser, MD
- Cole Eye Institute (Cleveland Clinic)
- Principal Investigator VISTA-DME (Eylea Phase 3)
- Principal Investigator VIEW (Eylea Phase 3)
- Founder SKS Ocular (company acquired 2014)

David Boyer, MD
- Retina Vitreous Associates Medical Group
- Principal Investigator COPERNICUS (Eylea Phase 3)
- Principal Investigator VIBRANT (Eylea Phase 3)
Safety studies in patients with retinal disease provide early insight into biological activity in heterogeneous population

<table>
<thead>
<tr>
<th></th>
<th>DME Study</th>
<th>Wet-AMD study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>44</td>
<td>44</td>
</tr>
<tr>
<td>Number of Treatment Arms</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Primary Outcome</td>
<td>Safety</td>
<td></td>
</tr>
<tr>
<td>Secondary Outcome:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Biological activity:</td>
<td></td>
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<tr>
<td></td>
<td>- Retinal thickness changes via Optical Coherence Tomography (OCT or standard retinal imaging, reviewed by core lab)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Change in Visual Acuity (best corrected VA)</td>
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</table>
Phase I/II clinical trial design focused on safety

Recorded at each visit:
- Adverse events
- Retinal thickness by OCT
- Visual acuity
Positive safety and tolerability

- Assessed safety in 88 patients
- No signs of corneal toxicity
- No drug-related Significant Adverse Events (SAE’s)
- Observed events are highly characteristic of populations evaluated

<table>
<thead>
<tr>
<th></th>
<th>DME Study</th>
<th>Wet-AMD Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocular Adverse Events (AEs)</td>
<td>7 (1 possibly related to SF0166 – conjunctivitis)</td>
<td>5 (1 possibly related to SF0166 – dry eye)</td>
</tr>
<tr>
<td>Non-ocular, not drug related,</td>
<td>6 (hyperglycemia, dizziness, pneumonia, septic diabetic foot ulcer, TIA,</td>
<td>1 (peripheral artery thrombus)</td>
</tr>
<tr>
<td>serious adverse events (SAEs)</td>
<td>worsening of cardiomyopathy)</td>
<td></td>
</tr>
<tr>
<td>Non-ocular AEs</td>
<td>33 (only 1 assessed as probably drug related – itching)</td>
<td>11 (1 assessed as probable (headache), one as possible (dysgeusia))</td>
</tr>
</tbody>
</table>
Example: normal OCT scan

OCT Scan of Normal, Healthy Eye and Identification of Retinal Layers

ILM: Inner limiting membrane
IPL: Inner plexiform layer
INL: Inner nuclear layer
OPL: Outer plexiform layer
ONL: Outer nuclear layer

ELM: External limiting membrane
IS/OS: Junction of inner and outer photoreceptor segments
OPR: Outer segment PR/RPE complex

NFL: Nerve fiber layer
GCL: Ganglion cell layer
RPE: Retinal pigment epithelium
+ Bruch’s Membrane

Fovea

INL  IPL  ILM  GCL  NFL
OPL  ONL  ELM  IS/OS  OPR  RPE  Choroid  Bruchs Membrane
Example: OCT scan of a DME patient

Retinal Thickness RT

Fluid
Responder: DME patient 103002

Day 0: Baseline

- VA: 56
- CRT: 530

28 days on drug

- VA: 61
- CRT: 327 (-202)

Day 56: 28 days off drug

- VA: 58
- CRT: 267 (-263)
Responder: DME patient 103014

Day 0: Baseline

VA: 65
CRT: 404

28 days on drug

VA: 65
CRT: 288 (-116)

Day 56: 28 days off drug

VA: 68
CRT: 243 (-161)
Example: OCT scan in a wet-AMD patient

Choroidal neovascularization (CNV)

Subretinal Fluid (SRF)
Responder: wet-AMD patient 108002

VA: 34
CRT: 579
SFT: 272

VA: 58
CRT: 335 (-244)
SFT: 180 (-91)

Post Rescue
VA: 65
CRT: 194 (-384)
SFT: 53 (-218)
Responder: wet-AMD patient 116002

VA: 67
CRT: 240
SFT: 51

VA: 80
CRT: 220 (-20)
SFT: 41 (-10)

VA: 80
CRT: 191 (-49)
SFT: 0 (-51)
Evidence of biological effect

Clear evidence SF0166 reaches the retina and has a biological effect despite heterogeneous patient populations in DME & wet-AMD

<table>
<thead>
<tr>
<th></th>
<th>DME Study</th>
<th>Wet-AMD Study</th>
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</thead>
<tbody>
<tr>
<td>Number of Patients Completed</td>
<td>40</td>
<td>42</td>
</tr>
<tr>
<td>Responders*</td>
<td>21 (53%)</td>
<td>9 (21%)</td>
</tr>
</tbody>
</table>

*definition

- Assessed as reduction in retinal thickness per OCT
- Defined as reduction in retinal thickness, elimination or significant reduction of subretinal fluid and clinical judgement

SciFluor is further evaluating results of patient subsets of each patient population

- DME patients often are easier to treat and progress more slowly.
- Sample included significantly more treatment-naïve patients relative to wet-AMD sample
- Wet-AMD patients often can go blind much more rapidly and typically do not spontaneously improve significantly without therapy.
- Sample included significantly fewer treatment-naïve patients
Summary of results of DME and wet-AMD studies

- Both Phase I/II studies were successful (positive)
- Excellent safety profile in 88 patients
- Evidence of biological activity seen in both studies

- Data strongly support advancing SF0166 into Phase 2 clinical development for DME and wet-AMD

- Management and Scientific Advisory Board developing trial designs, outcomes, patient populations and enrollment criteria for Phase 2, recognizing that visual acuity is a primary endpoint for most US approvals and retinal thickness is a valuable secondary outcome
Phase 2 – potential trial design

The role for a safe eye droplet with biological activity can be diverse depending on patient population and stage of disease; SciFluor may design different trials for DME and wet-AMD

- Primary outcomes: safety and visual acuity
- Secondary outcomes: retinal thickness
- N = 150 - 200
- ≥ 3 dose groups
- 3-month treatment duration
- 3-month follow up duration
- Estimated $10M and ~1 year (per trial)
### Issued patents: significant runway; 100% owned by SciFluor (no royalties)

#### Issued SciFluor SF0166 patents

<table>
<thead>
<tr>
<th>Retinal diseases</th>
<th>Patent No.</th>
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<th>20-year Term</th>
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<td>US 8,901,144</td>
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<td>US 9,266,884</td>
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<td>Bone resorption</td>
<td>EP 2953948</td>
<td>9/27/2017</td>
<td>2034</td>
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| **Disruptive innovation solving important problem** | • >50m people with retinal diseases leading to blindness  
• Current injectables cause significant patient discomfort and cost |
| **Favourable market dynamics** | • Revenues for injectable drugs for DME and wet-AMD exceed $8 billion  
• Growing market: ageing population and increasing diabetes incidence |
| **Sustainable competitive advantage** | • Patent protection: composition of matter and method of use  
• Clear cost and patient comfort advantages versus injectables  
• Non-injectable alternatives: pre-clinical, or with poor clinical results |
| **Route to widespread adoption** | • Injectables have established reimbursement codes  
• SF0166 would be distributed through standard pharmacy chains |
| **Capable management, with aligned interests** | • Leadership team includes world-leading experts in drug development with track record of producing compounds with >$1 billion in revenue  
• Live search for full-time CEO |
| **Establish potential for competitive tension** | • Obvious attractions to owners of injectable assets  
  o Defensive measure (if monotherapy)  
  o Offensive/Complementary (franchise expansion/combination)  
• IPO candidate at appropriate juncture |
Thank you