SciFluor™
Life Sciences
an allied minds company

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

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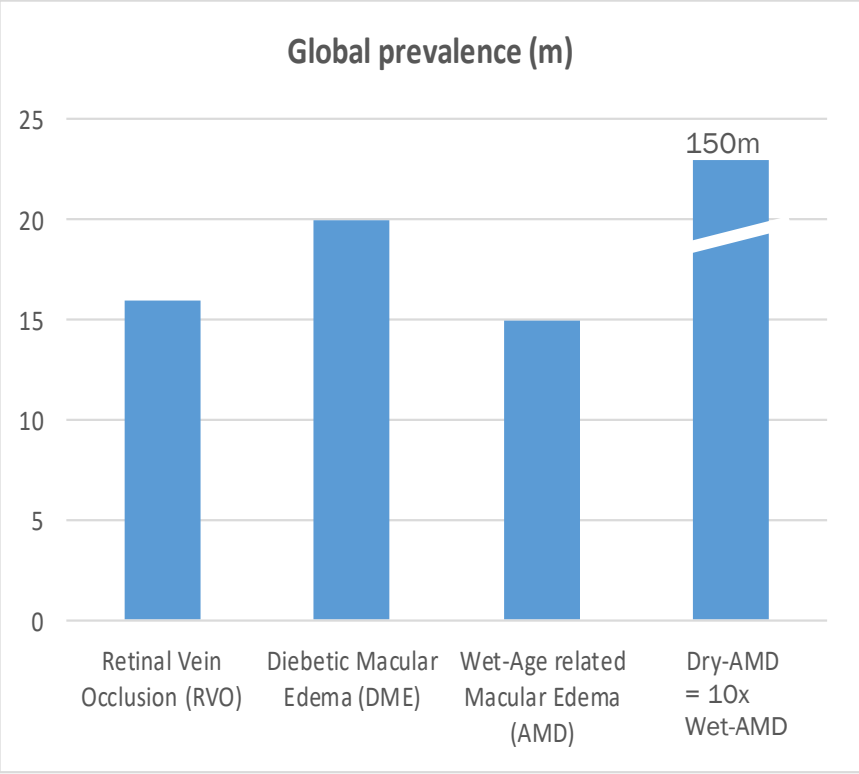
Massive underserved retinal disease opportunity

>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

	LUCENTIS RANIBIZUMAB	EYLEA
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

Competitive landscape

Diverse approaches are being pursued to address retinal disease

Ocular Injectables

Challenges

- Monthly injections
- Attempts to increase potency & reduce injection frequency

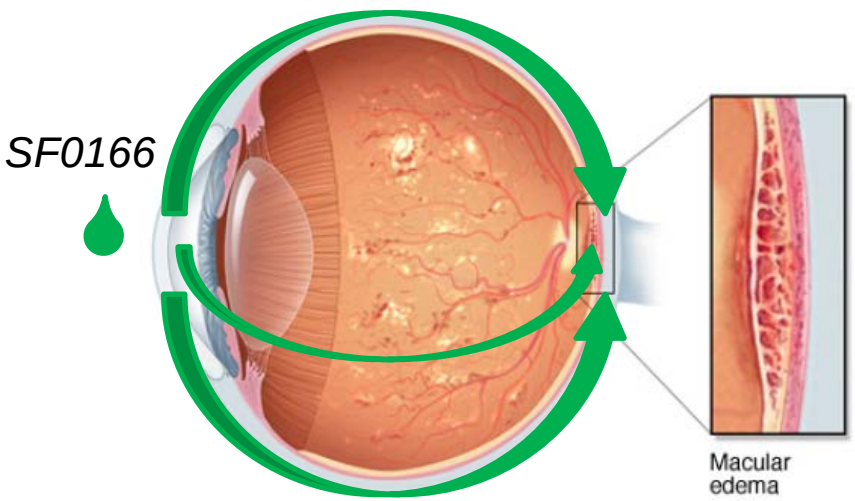
Topical eye droplet

- 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

2. Mechanism of action:
   Interrupts multiple disease pathways

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

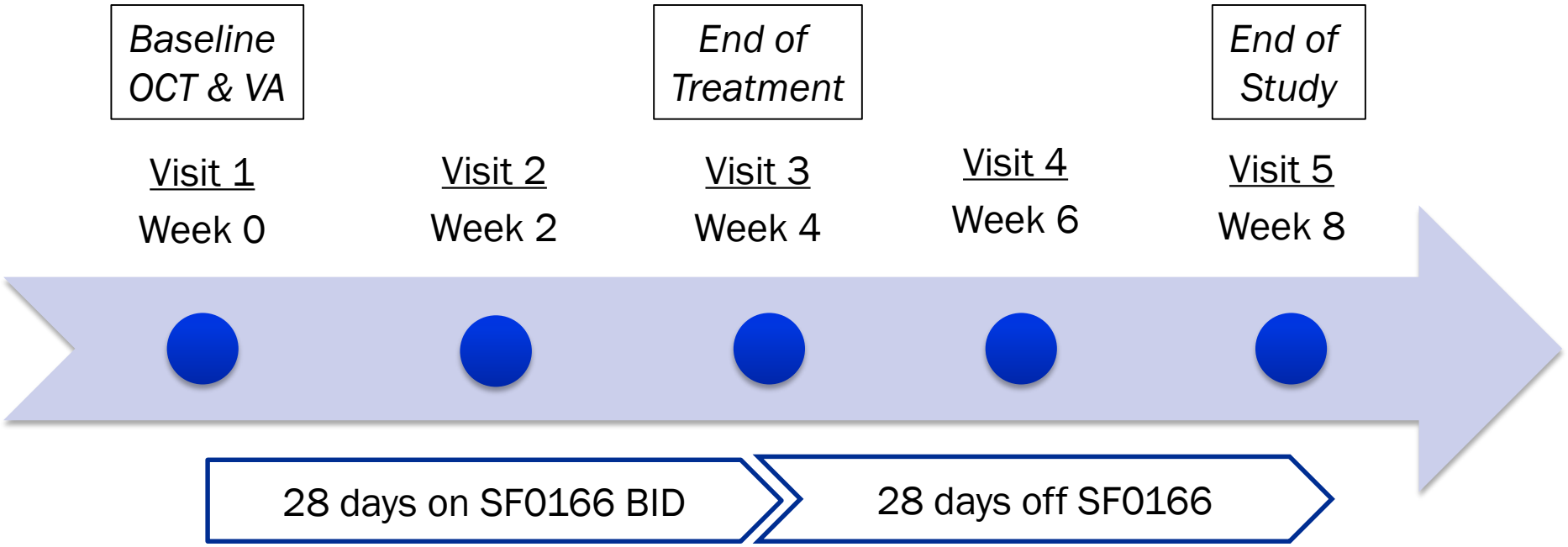
- Retina Vitreous Associates Medical Group
- Principal Investigator COPERNICUS (Eylea Phase 3)
- Principal Investigator VIBRANT (Eylea Phase 3)

Phase I/II clinical trials in DME & wet-AMD patients

Safety studies in patients with retinal disease provide early insight into biological activity in heterogeneous population

	DME Study	Wet-AMD study
Number of Patients	44	44
Number of Treatment Arms	2	
Primary Outcome	Safety	
Secondary Outcome:	Biological activity: ➢ Retinal thickness changes via Optical Coherence Tomography (OCT or standard retinal imaging, reviewed by core lab) ➢ Change in Visual Acuity (best corrected VA)	

Phase I/II clinical trial design focused on safety



Recorded at each visit:

- Adverse events
- Retinal thickness by OCT
- Visual acuity

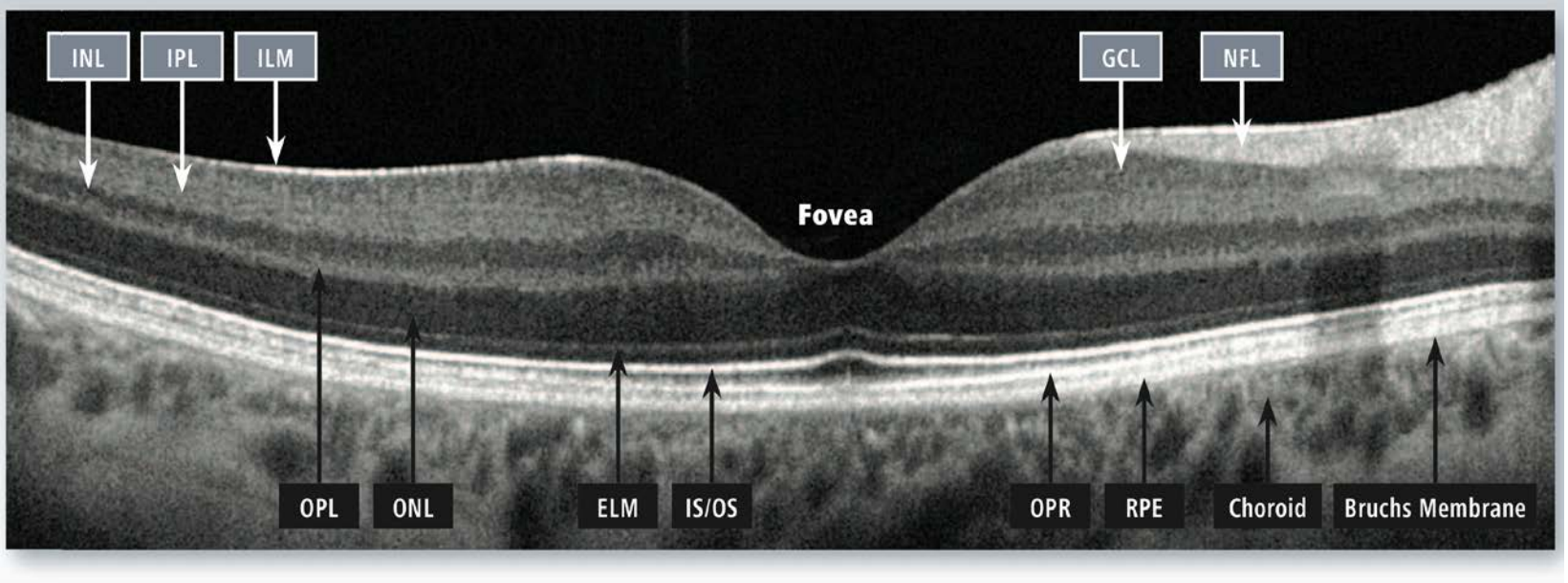
Positive safety and tolerability

- 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

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

Example: normal OCT scan

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

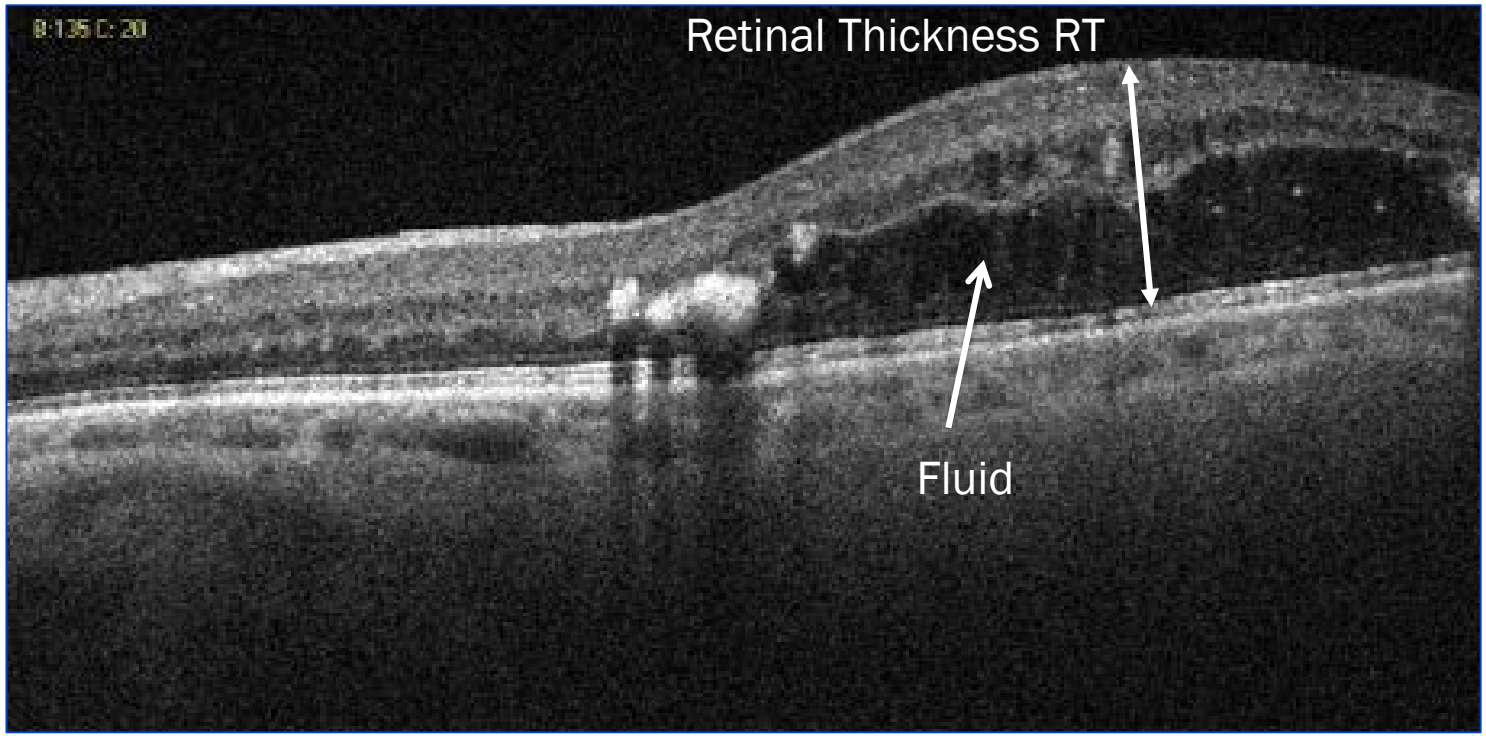


ILM: *Inner limiting membrane*
IPL: *Inner plexiform layer*
INL: *Inner nuclear layer*
OPL: *Outer plexiform layer*
ONL: *Outer nuclear layer*

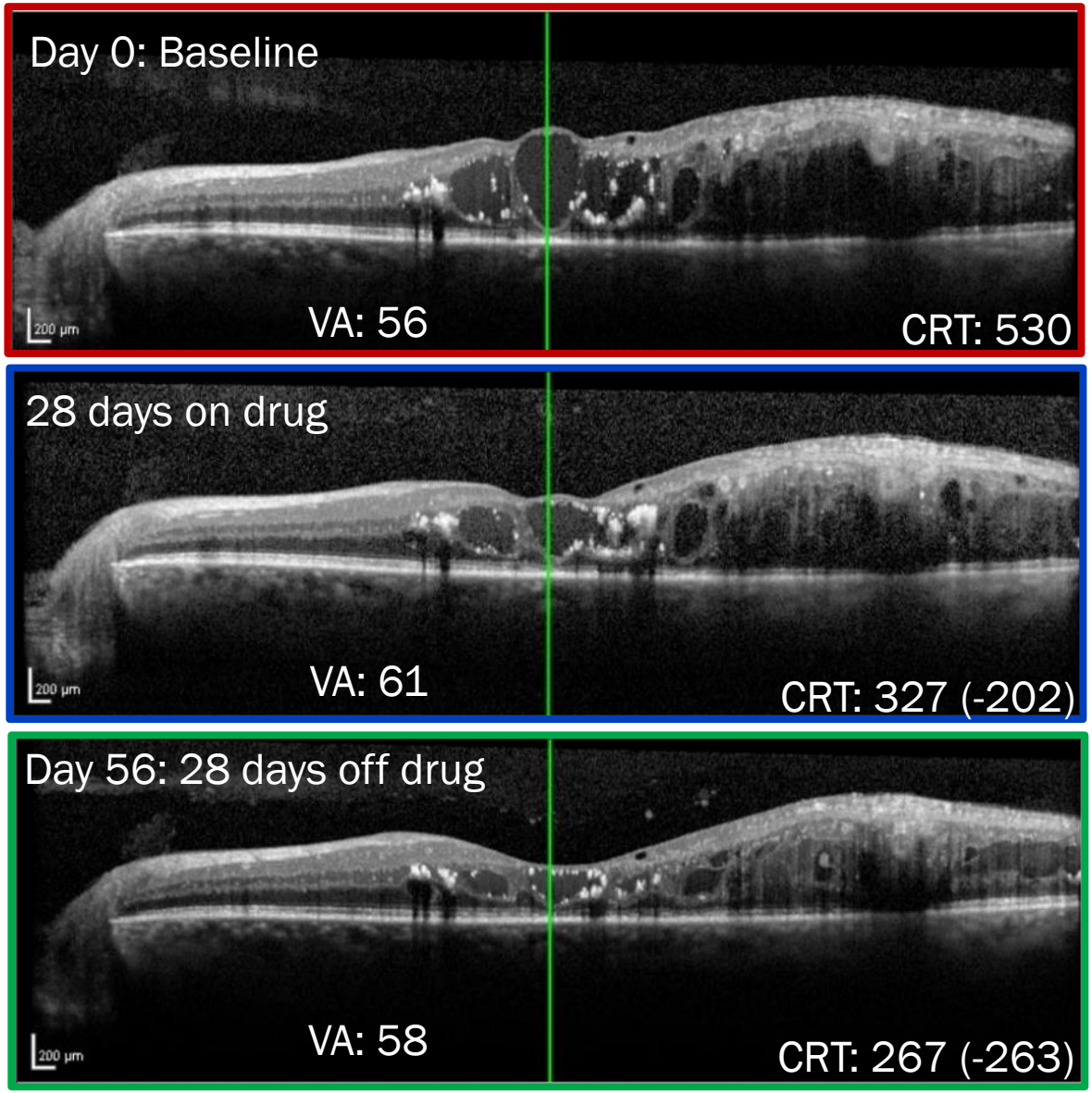
ELM: *External limiting membrane*
IS/OS: *Junction of inner and outer photoreceptor segments*
OPR: *Outer segment PR/RPE complex*

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

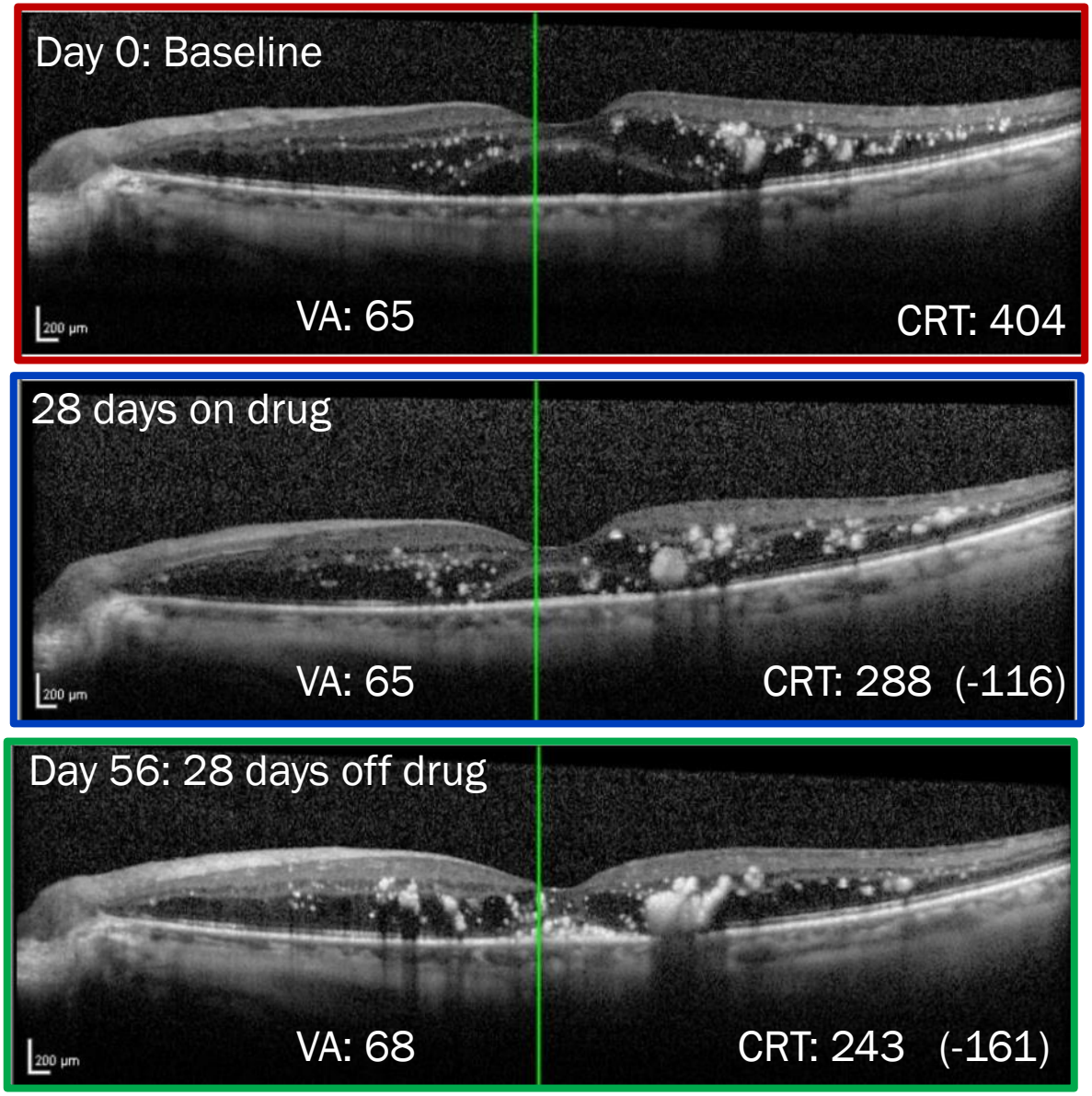
Example: OCT scan of a DME patient



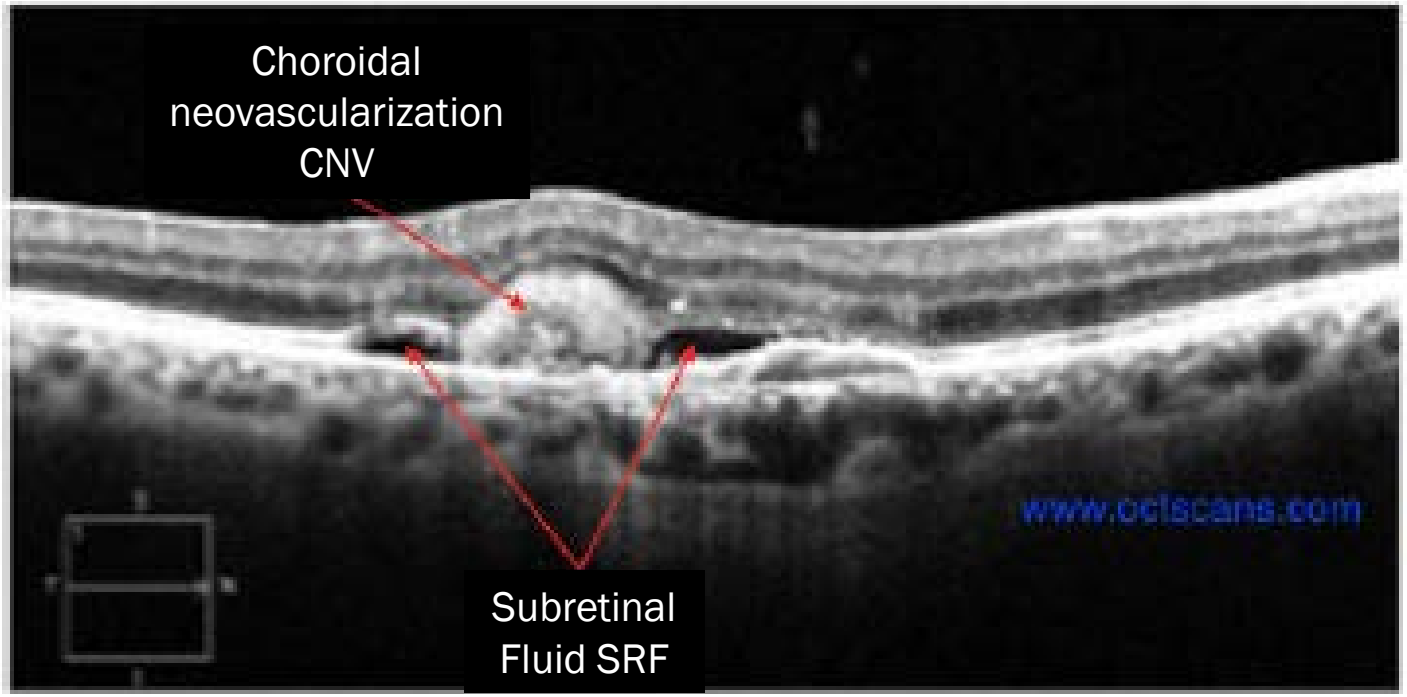
Responder: DME patient 103002



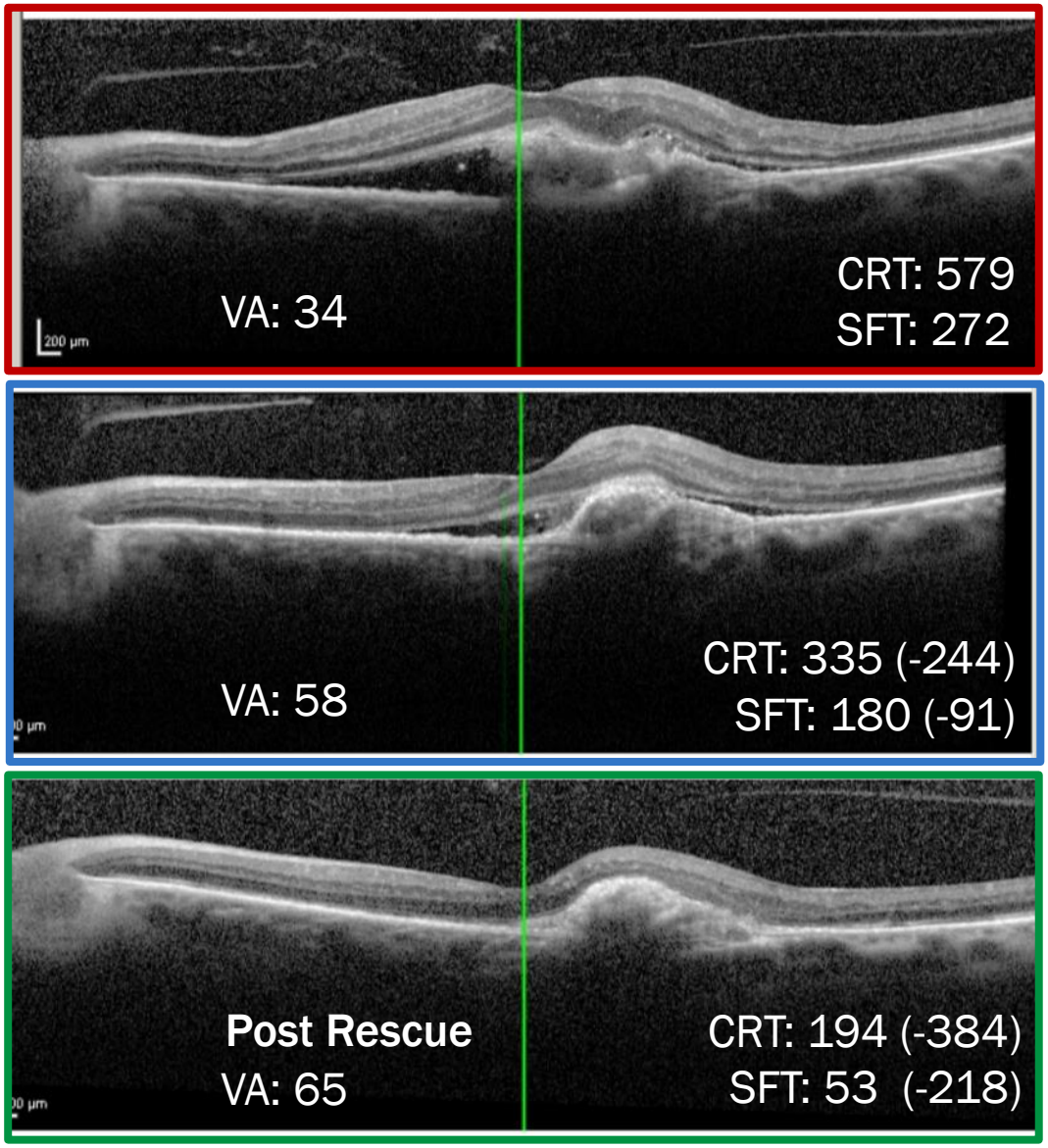
Responder: DME patient 103014



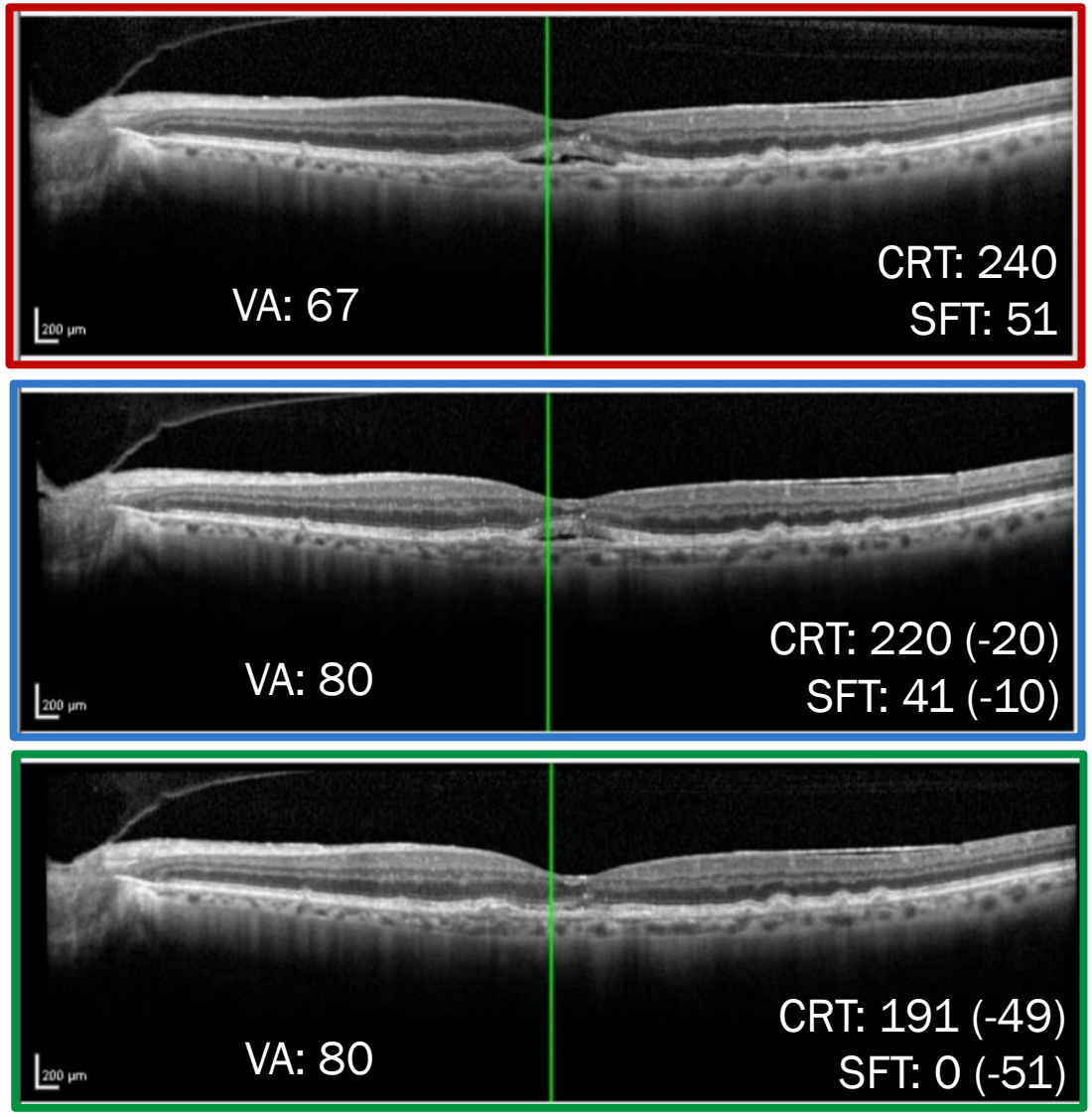
Example: OCT scan in a wet-AMD patient



Responder: wet-AMD patient 108002



Responder: wet-AMD patient 116002



Evidence of biological effect

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

	DME Study	Wet-AMD Study
Number of Patients Completed	40	42
Responders*	21 (53%)	9 (21%)
*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)

IP estate covering SF0166 and analogs

Issued patents: significant runway; 100% owned by SciFluor (no royalties)

Issued SciFluor SF0166 patents				
	Patent No.	**Issue Date**	**20-year Term**	**Comments**
Retinal diseases	**US 8,901,144**	**12/2/14**	**2034**	**SF0166 and analogs composition of matter**
	US 9,266,884	**2/23/16**	**2034**	**SF0166 and analogs (method of use)**
	US 9,518,053	**12/13/16**	**2034**	**SF0166 analogs (composition of matter)**
	US 9,593,114	**3/14/17**	**2034**	**SF0166 analogs (composition of matter)**
	US 9,717,729	**8/1/17**	**2034**	**SF0166 and analogs (methods of use)**
	EP 2953948	**9/27/2017**	**2034**	**SF0166 and analogs (composition of matter and methods of use)**
Bone resorption	**9,802,933**	**10/31/17**	**2034**	**SF0166 and analogs (methods of use)**

Unlocking a premium exit valuation

	Comment
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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Thank you