
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **May 2, 2019**

BioTime, Inc.

(Exact name of registrant as specified in its charter)

California
(State or other jurisdiction
of incorporation)

1-12830
(Commission
File Number)

94-3127919
(IRS Employer
Identification No.)

**1010 Atlantic Avenue
Suite 102
Alameda, California 94501**
(Address of principal executive offices)

(510) 521-3390
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 - Other Events

On May 2, 2019, BioTime announced that Dr. Eyal Banin, MD, PhD, Professor of Ophthalmology, Director, Center for Retinal and Macular Degenerations, Department of Ophthalmology at Hadassah-Hebrew University Medical Center, will be presenting updated results from BioTime's Phase I/IIa study of its lead product candidate, OpRegen[®], a retinal pigment epithelium cell transplant therapy currently in development for the treatment of dry age-related macular degeneration (AMD) with geographic atrophy (GA), today at the 2019 Association for Research in Vision and Ophthalmology Annual Meeting (ARVO 2019) in Vancouver, BC, Canada. Dr. Banin's presentation, entitled "*Phase I/IIa Study of Human Embryonic Stem Cell-Derived Retinal Pigment Epithelium Cells Transplanted Subretinally in Subjects with Advanced Dry-Form Age-Related Macular Degeneration: Interim Results*", is included as Exhibit 99.2 to this report, which is incorporated by reference.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated May 2, 2019
99.2	Presentation entitled "Phase I/IIa Study of Human Embryonic Stem Cell-Derived Retinal Pigment Epithelium Cells Transplanted Subretinally in Subjects with Advanced Dry-Form Age-Related Macular Degeneration: Interim Results"

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOTIME, INC.

Date: May 2, 2019

By: /s/ Brian M. Culley

Brian M. Culley
Chief Executive Officer



BIOTIME PRESENTS UPDATED DATA FROM OPREGEN[®] PHASE I/IIA CLINICAL STUDY AT THE ASSOCIATION FOR RESEARCH IN VISION AND OPHTHALMOLOGY ANNUAL MEETING

Treatment with OpRegen[®] Continues to be Well Tolerated with Signs of Structural Improvement in the Retina Observed in Some Patients

ALAMEDA, CA – May 2, 2019 – [BioTime, Inc.](#) (NYSE American and TASE: BTX), a clinical-stage biotechnology company developing new cellular therapies, announced that updated results from a Phase I/IIa clinical study of its lead product candidate, OpRegen[®], a retinal pigment epithelium (RPE) cell transplant therapy currently in development for the treatment of dry age-related macular degeneration (AMD) with geographic atrophy (GA), will be presented today at the [2019 Association for Research in Vision and Ophthalmology Annual Meeting](#) (ARVO 2019) in Vancouver, BC, Canada. Data from the study demonstrate that treatment with OpRegen continues to be well tolerated and in some patients, signs of structural improvement in the treated areas of the retina have been observed. Of note, early data from Cohort 4 patients with earlier-stage dry-AMD and smaller areas of GA remain encouraging, with indications of the continued presence of the transplanted OpRegen cells and improvements in visual acuity.

Data presented at ARVO 2019 showed that both the surgical procedure and the OpRegen cells were generally well tolerated with no unexpected adverse events or treatment-related systemic serious adverse events reported in the first fifteen patients enrolled to date. The most common and expected ocular adverse events were the formation of mild epiretinal membranes (ERM). One instance of retinal detachment occurred in a patient who was legally blind prior to treatment. The event was not able to be assigned as related to treatment, procedure, or to the combination, and the patient continued in the study following successful surgical repair. One instance of a severe ERM required surgical removal, which was successful, and the subject continues to demonstrate improved visual acuity from baseline following OpRegen administration.

Imaging of several patients from Cohorts 1, 2 and 3, and of particular interest, those from Cohort 4 (n=3) with better baseline vision, demonstrated sustained structural improvement within the retina and evidence of the continued presence of the transplanted OpRegen cells. Within the area of the OpRegen cell transplant, signs of a reduction and change in drusen material, as well as improvements or possible restorations of the ellipsoid zone and RPE layers, have persisted. The photoreceptor layer and ellipsoid zone assumed a more regular structural appearance in areas of the transition zone where OpRegen was administered, suggesting potential structural restoration of the retina in areas receiving the RPE cells. This is of particular importance because in dry-AMD the structure of the retina can be impacted by the formation of excess drusen and ultimately death of RPE cells and photoreceptors, which are critical to sight. Other changes observed following OpRegen treatment persisted through the last time point examined (up to 3 years) and included subretinal pigmentation and hyper-reflective areas seen on optical coherence tomography (OCT). Additionally, asymmetrical, reduced growth of GA in the treated areas receiving OpRegen was observed in some subjects. These observations are being independently evaluated by the Doheny Eye Institute and Doheny Image Reading & Research Lab (DIRRL), Los Angeles, CA.

The Best Corrected Visual Acuity (BCVA) and areas of GA continued to remain largely stable in the treated eyes. Notably, the visual acuity of the first three Cohort 4 patients with better baseline vision have all seen improvements from baseline levels and will be followed for longer periods of time. Overall, OpRegen appears well-tolerated with preliminary evidence of improved structural changes and potential improvement in visual acuity following treatment observed in some patients.

Eyal Banin, MD, PhD, Professor of Ophthalmology, Director, Center for Retinal and Macular Degenerations, Department of Ophthalmology at Hadassah-Hebrew University Medical Center, the presenting author and one of the investigators participating in the study, presented data from the Phase I/IIa clinical study. A copy of Dr. Banin's presentation will be available on the [Events](#) section of BioTime's website concurrent with his presentation at ARVO 2019.

About OpRegen®

OpRegen is a RPE transplant therapy in Phase I/IIa development for the treatment of dry AMD, the leading cause of adult blindness in the developed world. OpRegen consists of a suspension of RPE cells delivered subretinally as an intraocular injection. RPE cells are essential components of the back lining of the retina and function to help nourish the retina including photoreceptors. OpRegen has been granted Fast Track designation from the U.S. Food and Drug Administration.

About BioTime, Inc.

BioTime is a clinical-stage biotechnology company developing new cellular therapies for degenerative retinal diseases, neurological conditions associated with demyelination, and aiding the body in detecting and combating cancer. BioTime's programs are based on its proprietary cell-based therapy platform and associated development and manufacturing capabilities. With this platform BioTime develops and manufactures specialized, terminally-differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed either to replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or administered as a means of helping the body mount an effective immune response to cancer. BioTime's clinical assets include (i) OpRegen®, a retinal pigment epithelium transplant therapy in Phase I/IIa development for the treatment of dry age-related macular degeneration, the leading cause of blindness in the developed world; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase I/IIa development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells currently in Phase I development for the treatment of non-small cell lung cancer. For more information, please visit www.biotimeinc.com.

Forward-Looking Statements

BioTime cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "project," "target," "tend to," or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to the potential improvement in visual acuity following treatment observed in some patients. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause BioTime's actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including, without limitation, risk and uncertainties related to: BioTime's ability to raise additional capital when and as needed, to advance its product candidates; BioTime's ability to develop and commercialize product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for BioTime's product candidates in a timely manner; the therapeutic potential of BioTime's product candidates, and the disease indications for which BioTime intends to develop its product candidates; BioTime's ability to conduct and design successful clinical trials, to enroll a sufficient number of patients, to meet established clinical endpoints, to avoid undesirable side effects and other safety concerns, and to demonstrate sufficient efficacy of its product candidates; developments by BioTime competitors that make BioTime's product candidates less competitive or obsolete; BioTime's ability to manufacture its product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture; the performance of third parties in connection with the development and manufacture of BioTime's product candidates, including third parties conducting clinical trials as well as third-party suppliers and manufacturers; the potential of BioTime's cell therapy platform, and BioTime's plans to apply its platform to research, develop and commercialize our product candidates; BioTime's ability, and the ability of its licensors, to obtain, maintain, defend and enforce intellectual property rights protecting BioTime's product candidates, and BioTime's ability to develop and commercialize its product candidates without infringing the proprietary rights of third parties; BioTime's ability to recruit and retain key personnel; and BioTime's ability to successfully integrate the operations of Asterias into BioTime. BioTime's forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. For a detailed description of BioTime's risks and uncertainties, you are encouraged to review its documents filed with the SEC including its recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. BioTime undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

BioTime Inc. IR

Ioana C. Hone

(ir@biotimeinc.com)

(510) 871-4188

Solebury Trout IR

Gitanjali Jain Ogawa

(Gogawa@troutgroup.com)

(646) 378-2949

###

**Phase I/IIa Study of Human Embryonic Stem Cell-Derived
Retinal Pigment Epithelium Cells Transplanted
Subretinally in Subjects with Advanced Dry-Form
Age-Related Macular Degeneration: Interim Results**

Eyal Banin, MD, PhD

Center for Retinal and Macular Degenerations (CRMD)

Department of Ophthalmology,

Hadassah-Hebrew University Medical Center, Jerusalem, Israel

On behalf of the participating investigators and clinical trial staff

Financial disclosures

Eyal Banin: Patent, Consultant; **Adiel Barak:** Investigator; **David Boyer:** Investigator, Consultant; **Diana V. Do:** Investigator, Consultant; **Rita Ehrlich:** Investigator; **Tareq Jaouni:** Investigator; **Richard McDonald:** Investigator; **David G. Telander:** Investigator; **Maria Gurevich:** Cell Cure Neurosciences, Employment; **Ohad Cohen:** Cell Cure Neurosciences, Employment; **Gary S. Hogge:** BioTime Inc., Employment; **Benjamin Reubinoff:** Cell Cure Neurosciences, Patent, Consultant

Study Sponsor

BioTime, Inc.

Cell Cure Neurosciences (a wholly-owned subsidiary of BioTime)

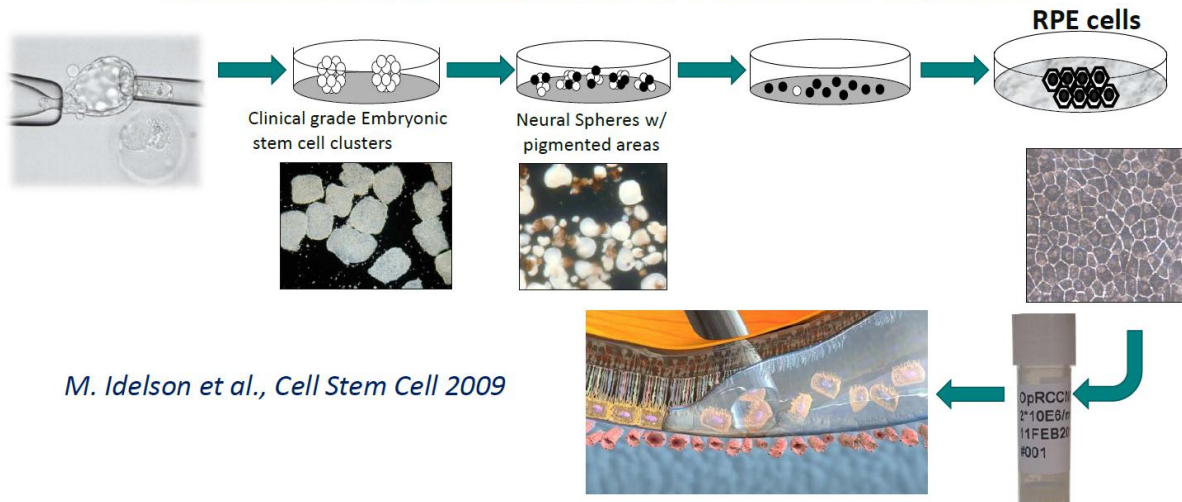
Participating principal investigators and sites

Adiel Barak, Sourasky Medical Center, Tel Aviv, Israel
David Boyer, Retina Vitreous Associates Medical Group Los Angeles, CA, USA
Diana V. Do, Byers Eye Institute, Stanford, Palo Alto, CA, USA
Rita Ehrlich, Rabin Medical Center, Petah Tikva, Israel
Tareq Jaouni, Hadassah-Hebrew University Medical Center, Jerusalem, Israel
Richard McDonald, West Cost Retina Group, San Francisco, CA, USA
David Telander, Retinal Consultants Medical Group, Sacramento, CA, USA

We wish to thank all subjects who are participating in this study

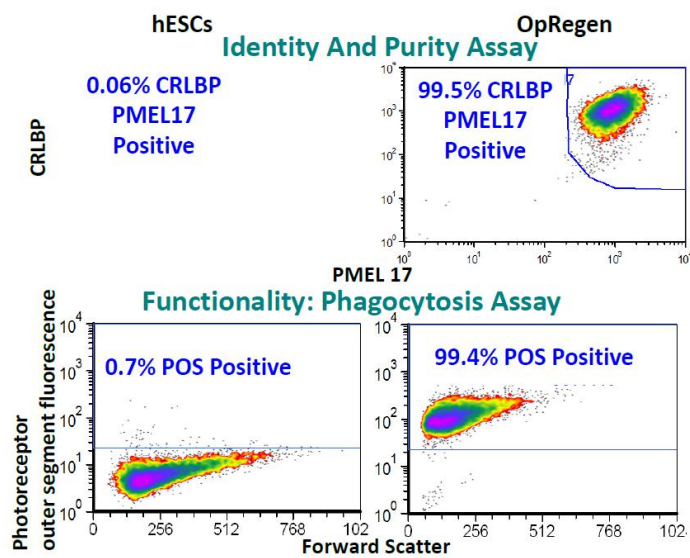
Human Embryonic Stem Cells (hESC) Derived Retinal Pigmented Epithelial (RPE) Cells – OpRegen[®]

Directed differentiation of hESC to RPE under GMP conditions

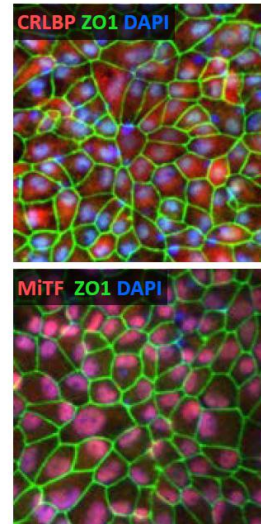


M. Idelson et al., Cell Stem Cell 2009

In Vitro Pre Clinical Data: Identity and Functionality

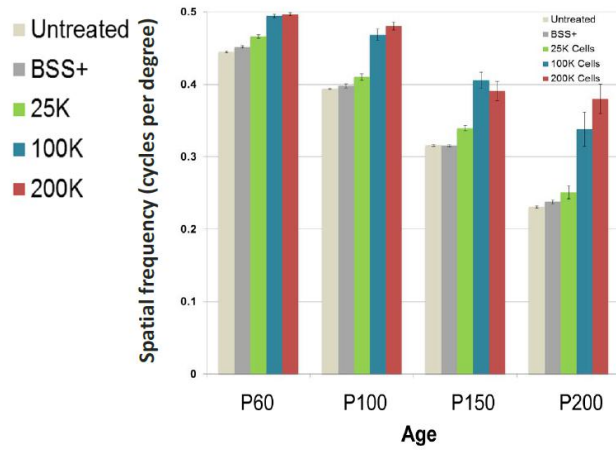


In-Vitro Immunofluorescence

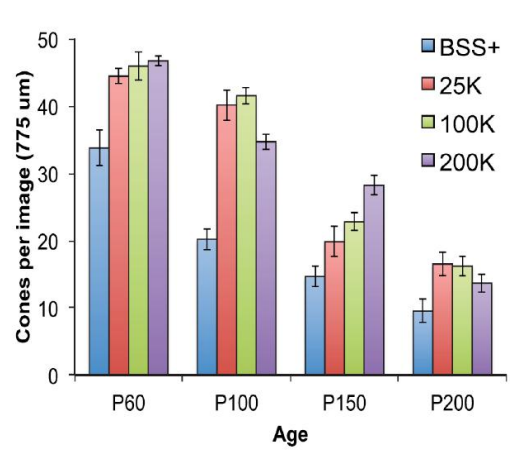


In-Vivo Pre Clinical Data: Efficacy

Optomotor Tracking Threshold In RCS Rats

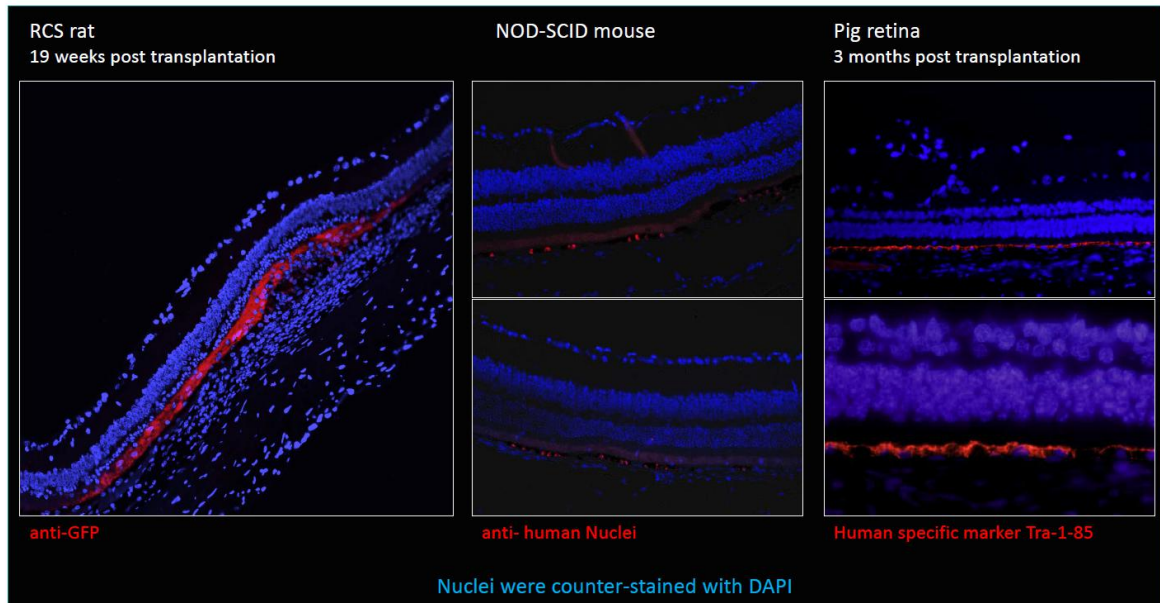


Cone quantification in RCS Rats



TJ McGill, et al. Transl Vis Sci Technol. 2017;6(3):17

Engraftment and survival of hESC-RPE in three animal species



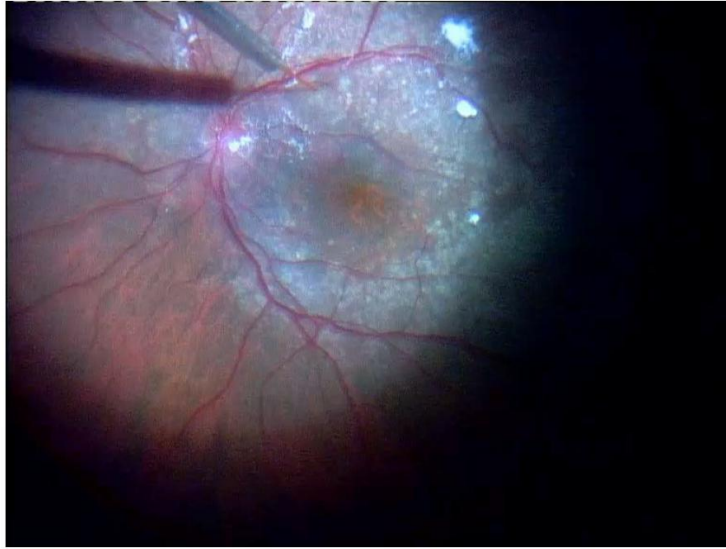
Study design, population, management

Parameter	Cohort 1-3 N=12	Cohort 4 N=12
Phase/design	Phase I-IIa; staggered design; IND (NCT02286089)	
Duration	Screening up to 8 Weeks; FU – 1 year; long term FU – 4 years	
Management	Central reading/central labs/ Independent DSMB/Advisory Committees	
Treated disease	Advanced Dry AMD and GA	
Dose	Cohort 1: 50K cells Cohort 2-3: up to 200K cells	Up to 200K cells
GA size – Central Reading assessment	$\geq 1.25\text{mm}^2 \leq 17 \text{mm}^2$	$\geq 4 \text{mm}^2$ and $\leq 11 \text{mm}^2$
BCVA	$\leq 20/200$	$\geq 20/64$ and $\leq 20/250$
Historical Growth of GA	NA	SQRT per year of $> 0.25 \text{mm}$
Cataract status	Not defined	Pseudophakic
Significant concomitant diseases exclusion (systemic/ocular)	Defined	

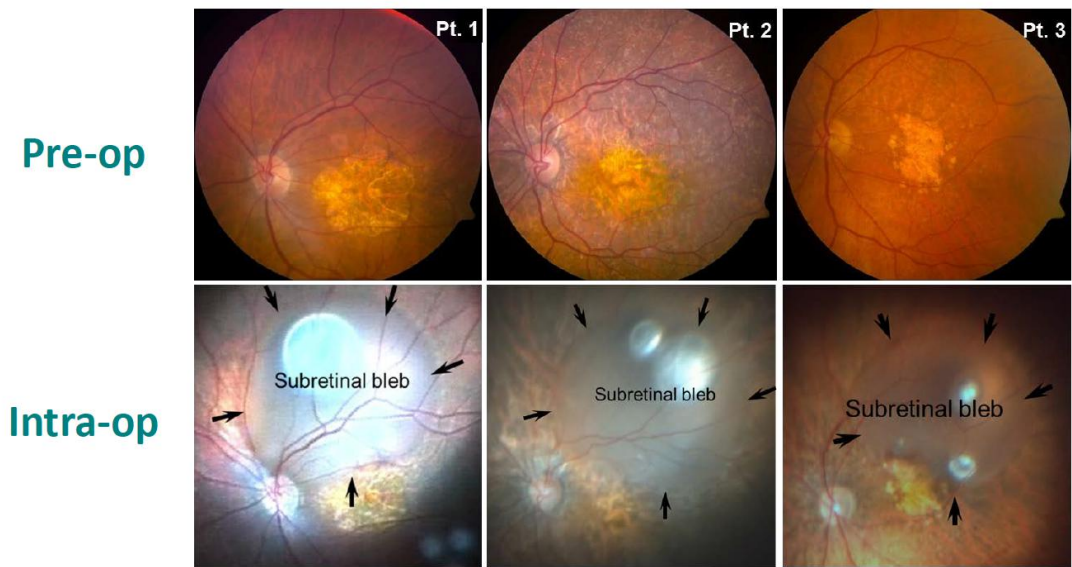
Study assessments

Endpoints	Assessments
Primary: Safety	Adverse Events
Secondary: Anatomical and Functional Ocular findings	Clinical / Imaging Outcomes <ul style="list-style-type: none">• BCVA• OCT• FAF• Fundus Photography• FQ25 QOL*• Reading Speed Test*• Microperimetry* <p>* Ongoing in Cohort 4 subjects</p>

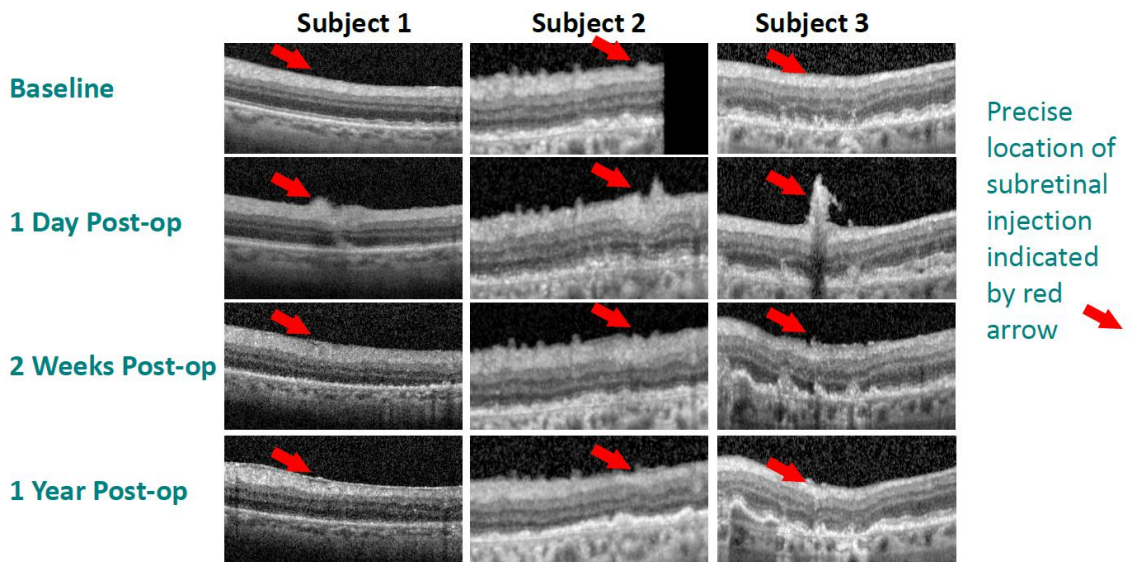
OpRegen® Transplantation



Representative Color Fundus Imaging



Rapid Healing of Injection Site



Baseline

1 Day Post-op


2 Weeks Post-op

1 Year Post-op

Subject 1

Subject 2

Subject 3

Precise location of subretinal injection indicated by red arrow 

Study Update

Study status

- Cohort 1-3 recruitment completed
- Cohort 4 recruitment ongoing

Cohort	1-3	4
N (%) of subjects screened	54 (100%)	17 (100%)
N (%) of screening failures	42 (78%)	14 (82%)
N (%) subjects treated	12 (22%)	3 (18%)
N (%) subjects dropout	1 (8 %)	0
Post-implantation cumulative FU period	15.1 years	1.7 years
Mean FU (days)	339.3 (SE ± 97.9)	208.7 (SE ± 25.5)
Median FU (days)	373.5 ((63*) 189-1067 days)	195.0 (173-258 days)

* Dropout subject

Baseline characteristics for cohorts 1-3 and 4

Cohort/ Parameter	1-3 N=12	4 N=3
Age: mean (SD/min-max)	78.3 (\pm 8.2/64.8-92.2) years	77.1 (\pm 3.1/74.6-80.6) years
ETDRS BCVA: mean (SD/min-max)	23.7(\pm 11.7/0-39) letters*	55 (\pm 13.5/42-59) letters*
GA area: mean (SD/min-max)	12.7(\pm 7/6-30) mm ²	7.1 (\pm 1.4/5.5-8.3) mm ²
Known duration of AMD: mean (SD/min-max)	100 (\pm 52.7/35.7-195.4) months	82 (\pm 23.7/66.8-99.2) months

*Conversion of ETDRS letters to approximate Snellen equivalent

23 = 20/400

39 = 20/160

42 = 20/160

55 = 20/80

59 = 20/63

Primary endpoints: systemic and ocular safety and tolerability-Part I

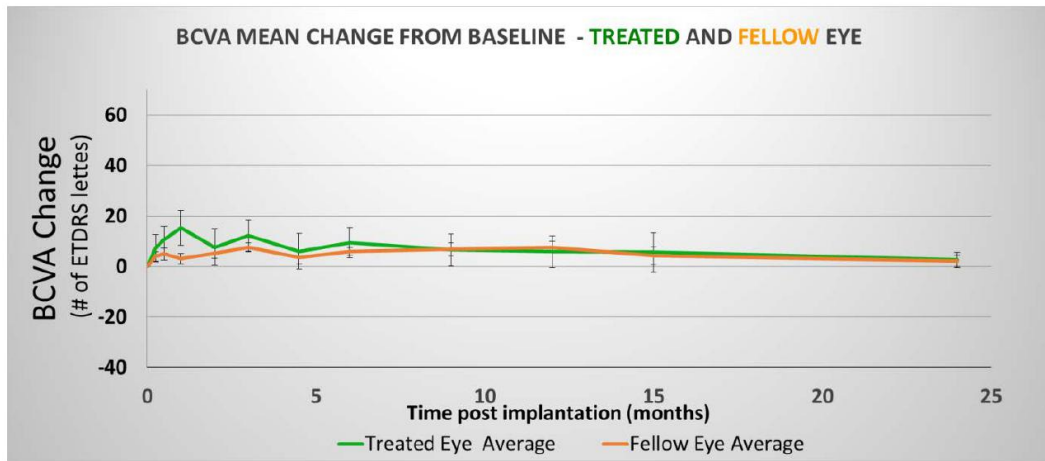
- Safety and Tolerability
 - BCVA remained largely stable over time in treated eyes
 - One cohort 4 subject experienced a marked improvement
 - One cohort 4 subject experienced a sharp decline due to ERM, BCVA returned to few letters above baseline after ERM peeling
 - One cohort 1 subject experienced a sharp improvement followed by a decline but yet above baseline
 - GA remained largely stable over time in treated eyes
 - No IOP elevations occurred
 - All subjects reported at least one AE (N=246)
 - Most AEs were of mild intensity (88.6%)
- Most frequently reported systemic disorders
 - Asthenia and malaise reported by 4 subjects
 - All others AEs reported were single events with no trends

Primary endpoints: systemic and ocular safety and tolerability-Part II

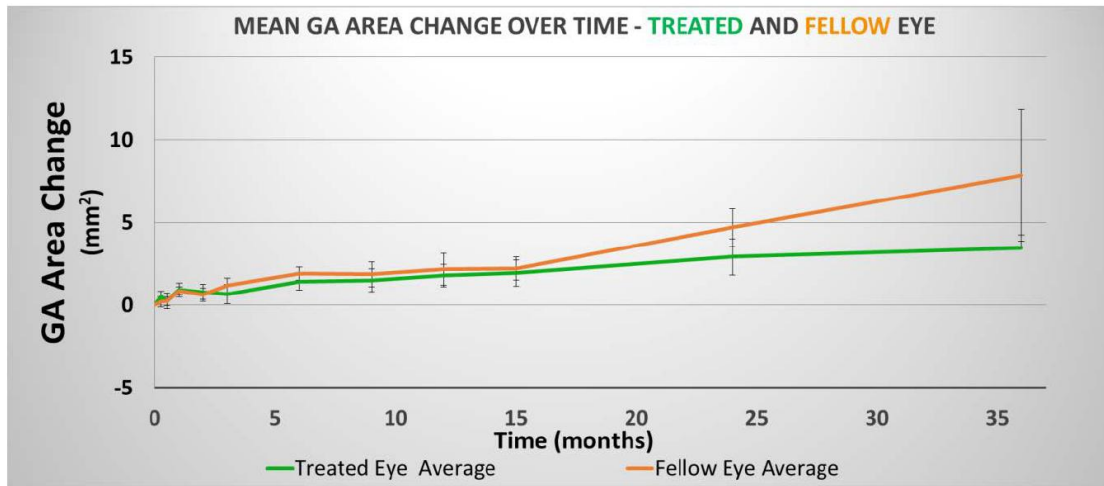
- Ocular Safety and Tolerability

- The most reported AEs were related to Eye Disorders System; most frequent were:
 - Conjunctival Hemorrhage after surgery – reported by 8/ 15, recovered rapidly
 - Eye irritation – reported by 1 subject
 - Subretinal fluid persisting over 24hr post-injection reported by 4 subjects, all absorbed within 72hr
 - Subretinal pigmentation – developed in 8 subjects (as reported by site)
 - One subject developed CNV over two years after implantation
 - Epiretinal Membrane (new/worsening) – reported by 13 subjects, most mild to moderate, one required interventional surgical peel, which was successful
 - Lamellar hole reported by 2 subjects (associated with ERM)
 - Retinoschisis (related to ERM) – reported by 1 subject
- Two Ocular SAE
 - Retinal detachment was reported in one subject 2 weeks after surgery. Unknown whether a result of surgical procedure, implanted cells, or a combination of events
 - In one subject a severe ERM developed rapidly after surgery – intervention required – ERM peel was performed successfully – BCVA improved to a few letters above baseline, retinal structure restored

Cohorts 1-3: BCVA change from baseline over time (n=12)



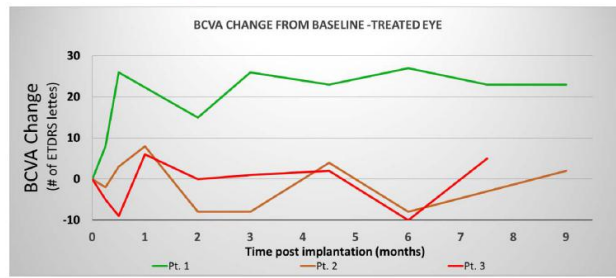
Cohorts 1-3: GA area change from baseline over time (n=12)



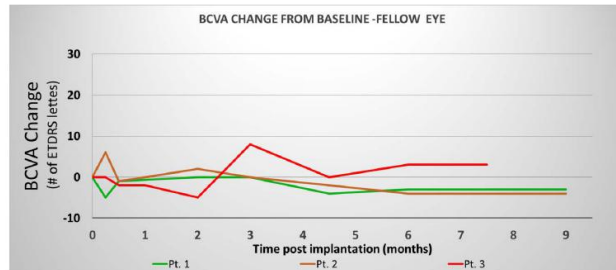
GA area as measured from FAF images by central reading center

Cohort 4: BCVA change from baseline over time (n=3)

Treated Eye

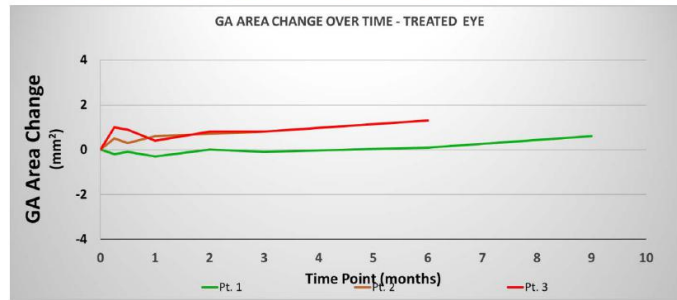


Fellow Eye

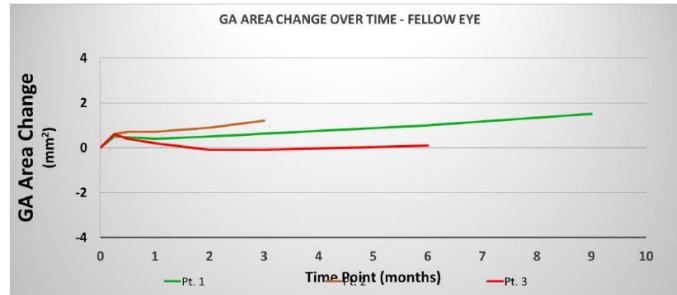


Cohort 4: GA area change from baseline over time (n=3)

Treated Eye



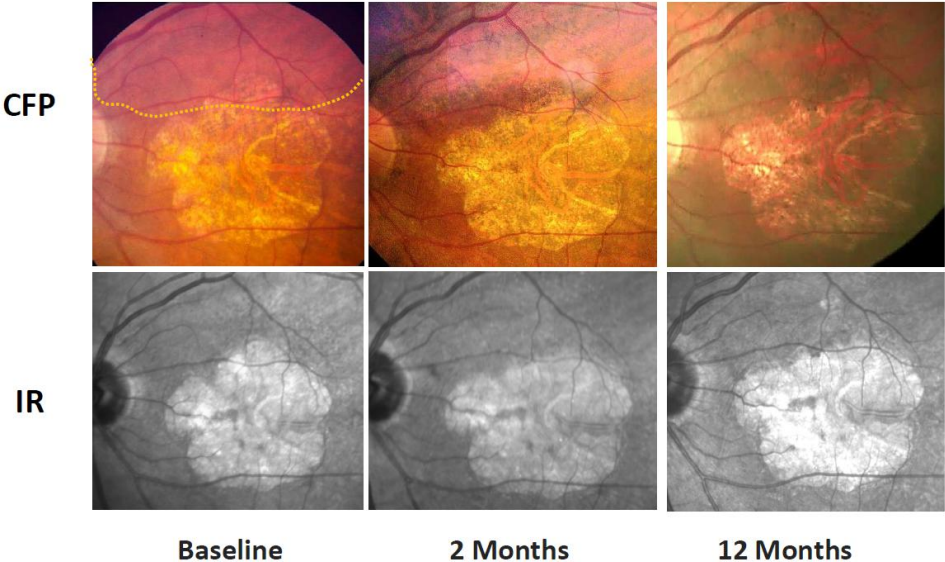
Fellow Eye



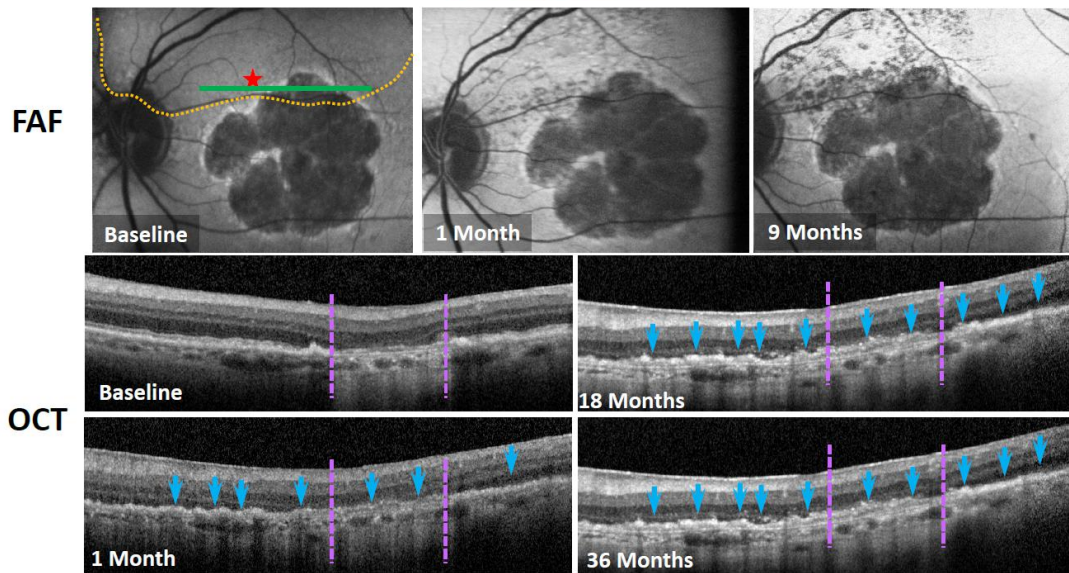
Study outcomes of secondary endpoints: Imaging findings that may support presence and survival of transplanted cells

- As per Reading Center, 10 out of 15 subjects show new subretinal hyperpigmentation after hESC-RPE transplantation
- In 7 out of 15 cases, irregular hyper-reflectivity at RPE level observed on OCT
- In 9 out of 15 cases hypo- and hyper-fluorescent spots observed within treated area on FAF

Subject 1

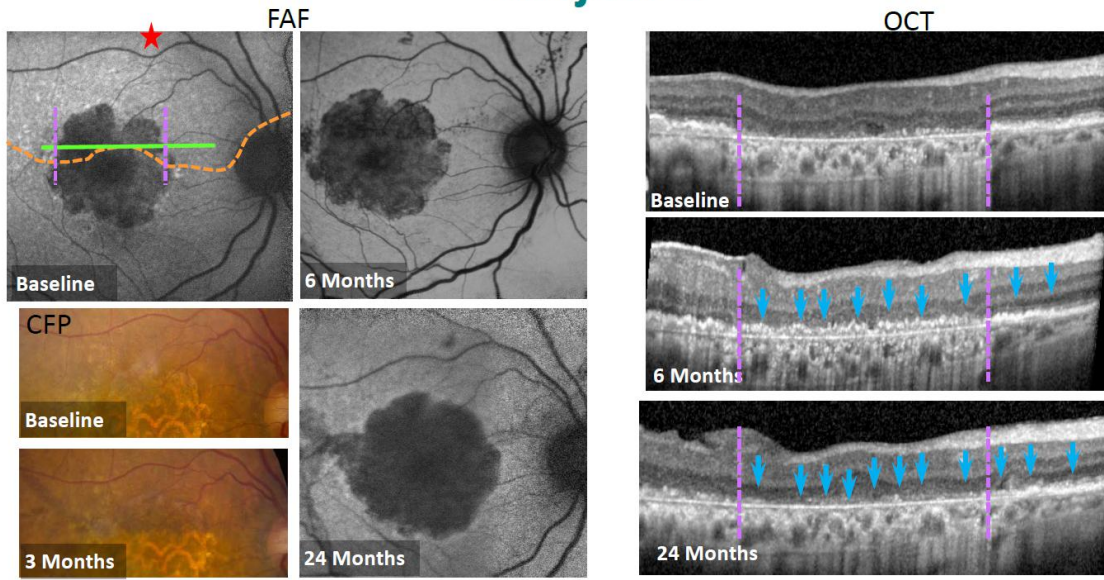


Subject 1



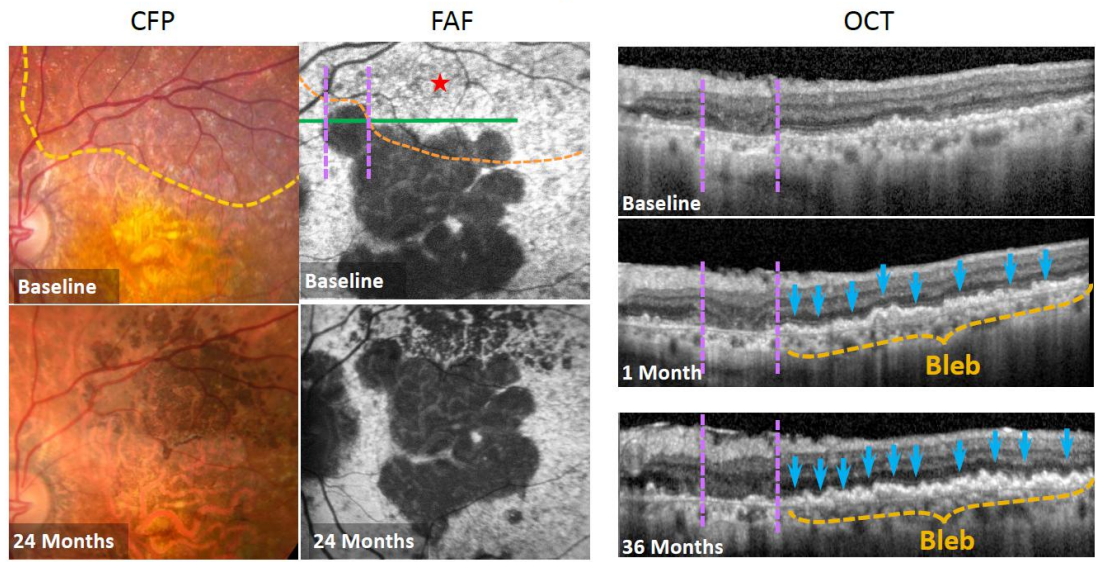
bleb border, Sub retinal injection location, GA border, Irregular hyper-reflectivity

Subject 4



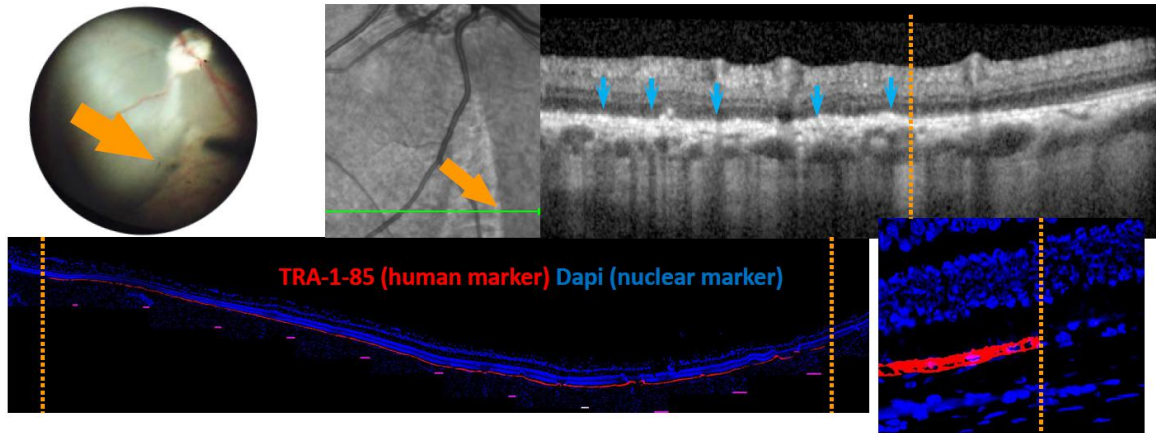
Bleb border, Subretinal injection location, GA border, Irregular hyper-reflectance

Subject 2



Bleb border, Subretinal injection location, GA border, Irregular hyper-reflectance

OpRegen engraftment and survival in swine

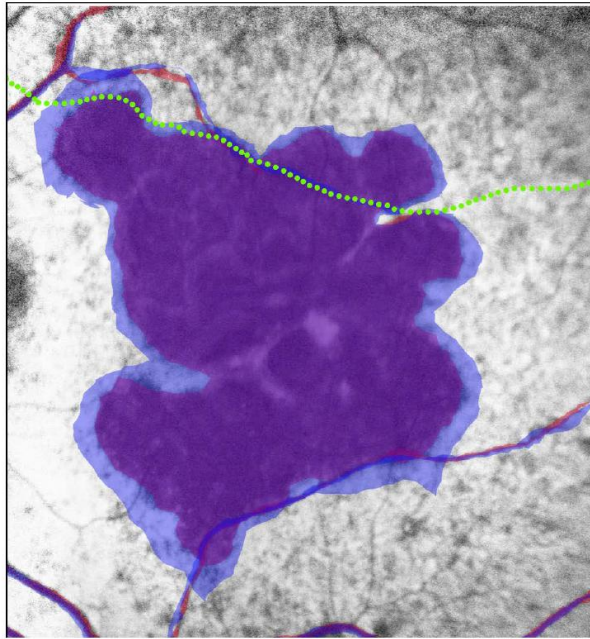


Bleb border, irregular hyper-reflectance in outer retina

Subject 2

GA at baseline (red-violet)
Versus 36 months (light blue)

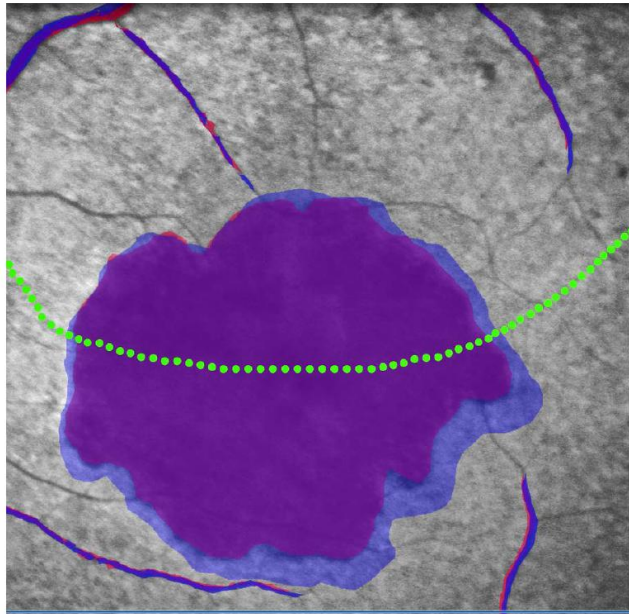
Dashed Green line- bleb border



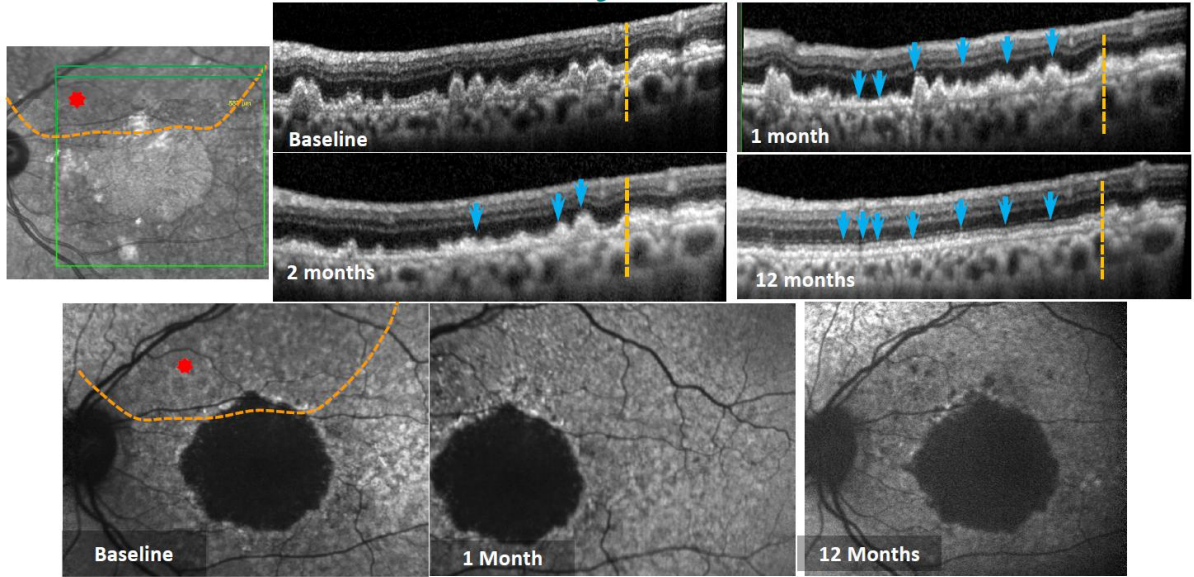
Subject 9

GA at baseline (red-violet)
Versus 12 months (light blue)

Dashed Green line- bleb border

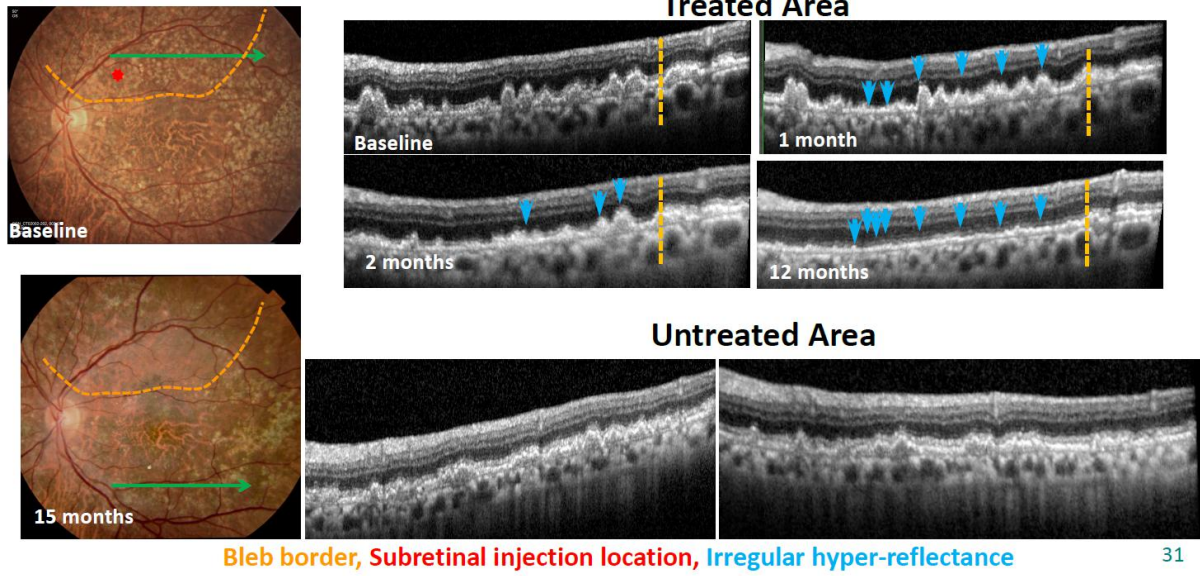


Subject 8

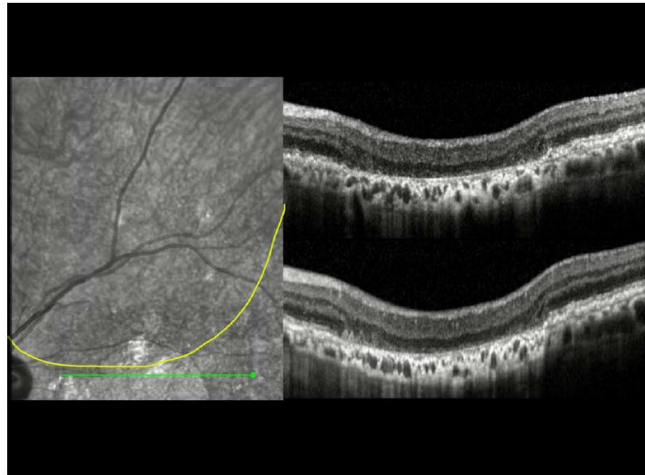


Bleb border, Subretinal injection location, Irregular hyper-reflectance

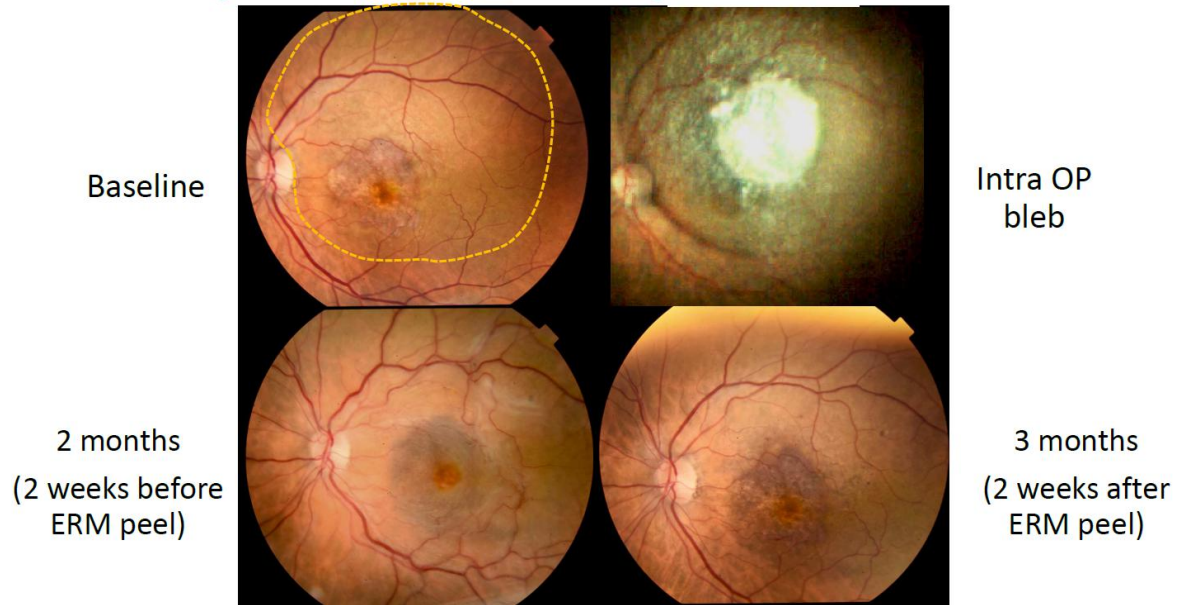
Selected images of Drusen reduction



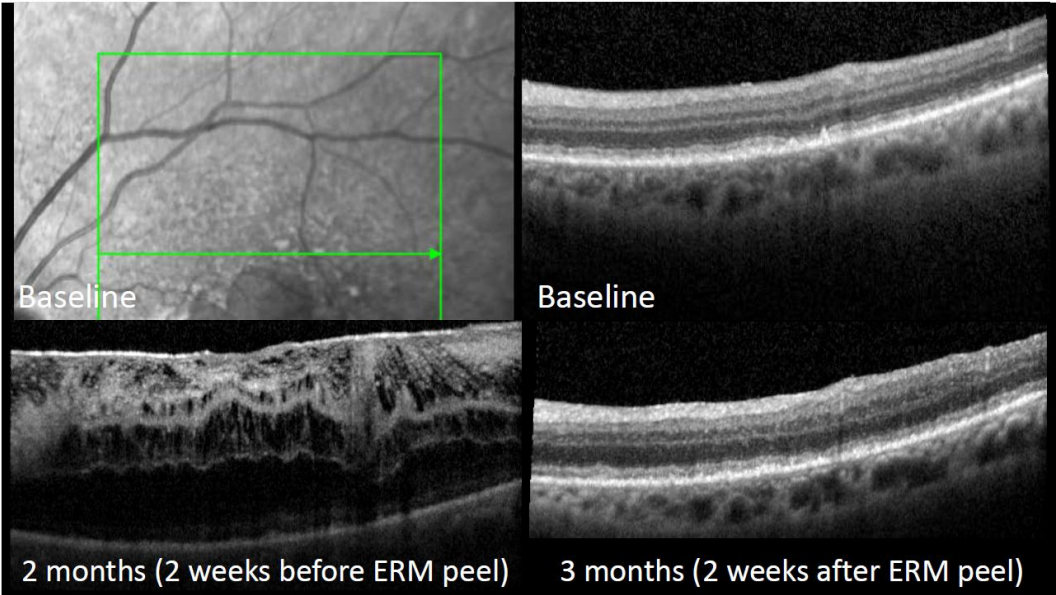
Subject 8: Baseline vs 12 months – Shows changes are being maintained



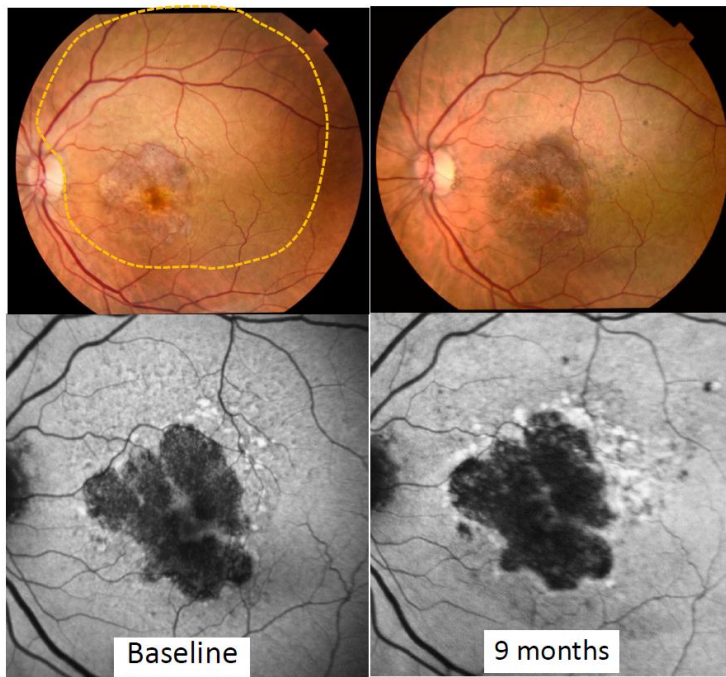
Case Report- Cohort 4, Subject 14



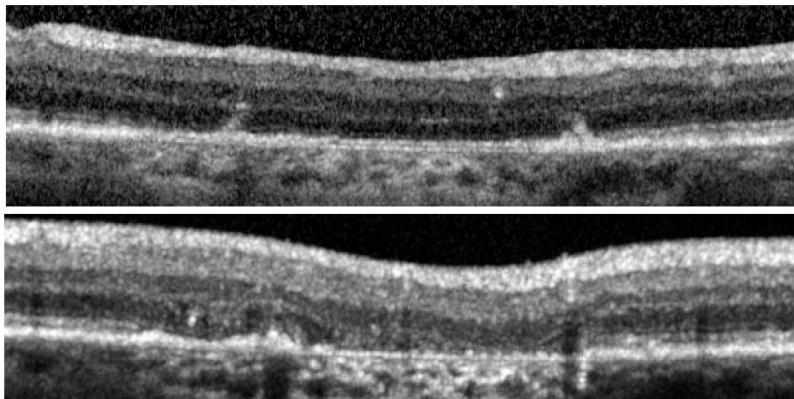
Case Report



Case Report



Case Report

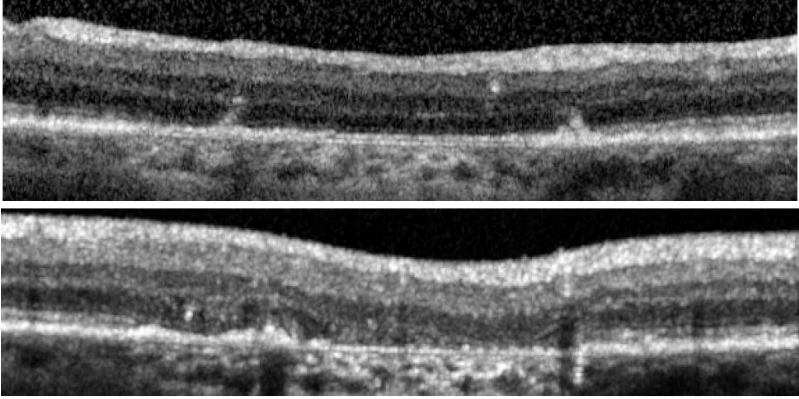


Case Report

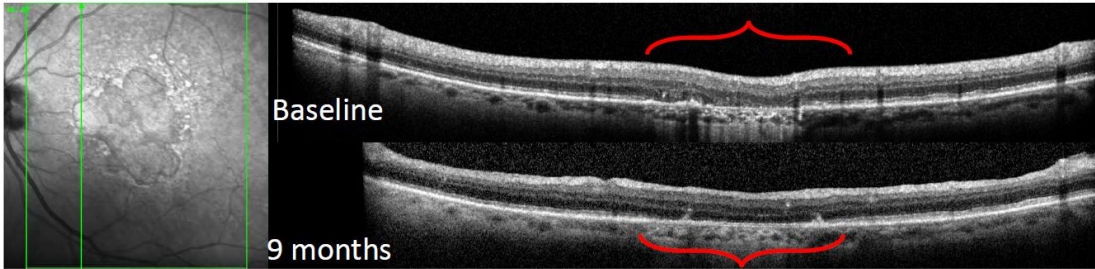
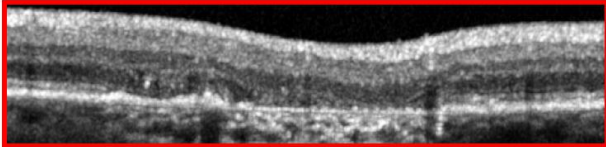
9 months



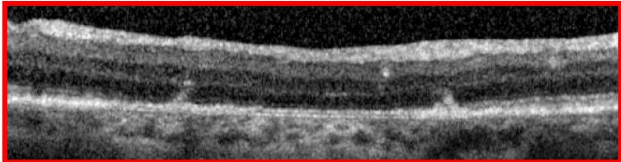
Baseline



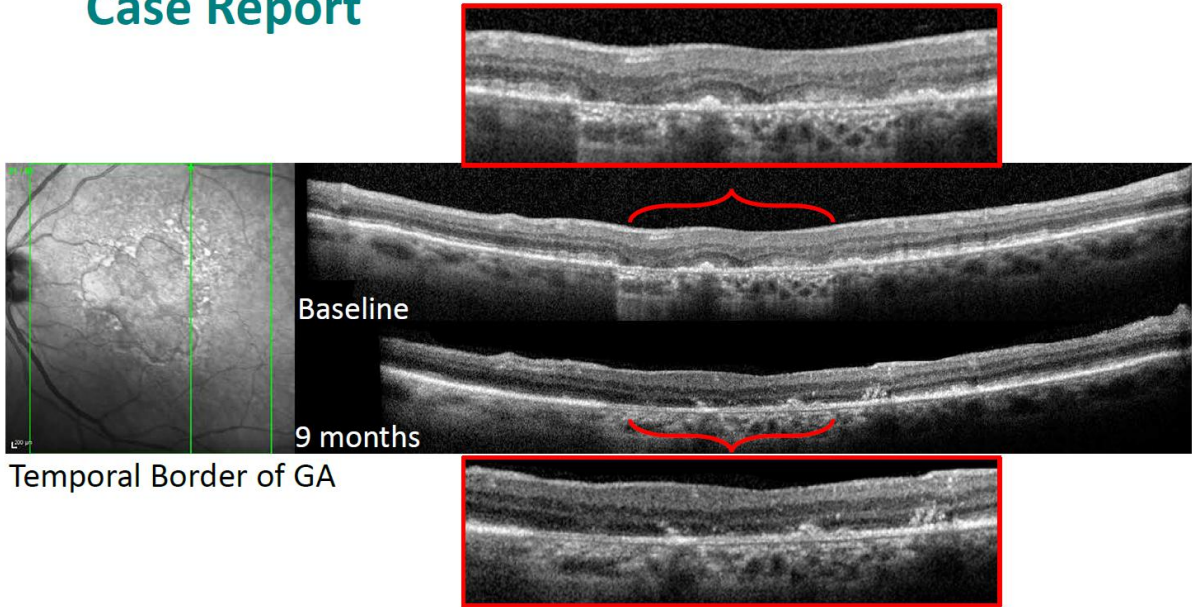
Case Report



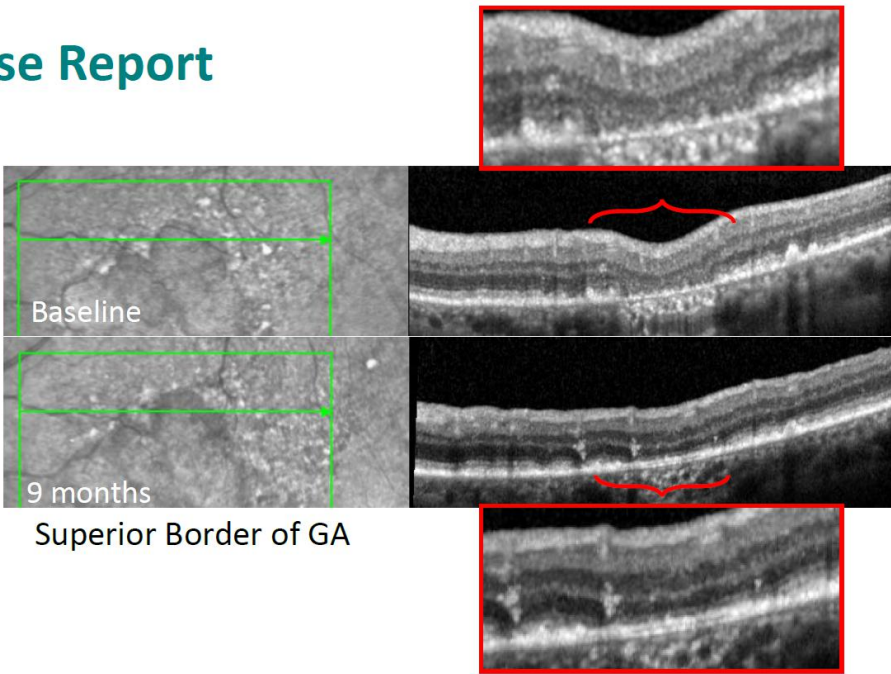
Nasal Border of GA



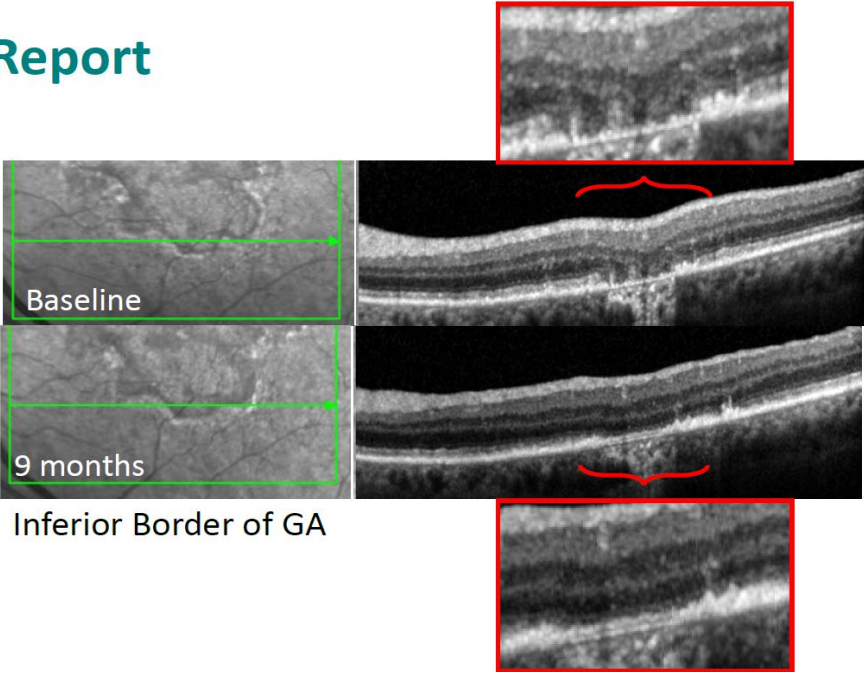
Case Report



Case Report



Case Report

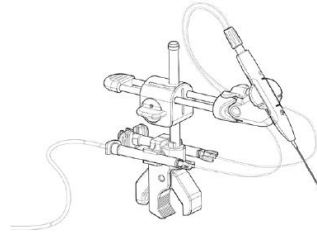
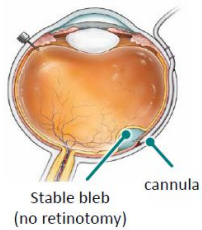


Summary (I)

- Following subretinal transplantation of OpRegen (hESC-RPE) in suspension there is rapid healing of the injection sites, and visual acuity remained largely stable throughout the study with follow-up of up to 36 months in the first-treated subjects
- Subretinal pigmentation in the treated area is observed in 10/15 subjects, which has remained stable for up to 3 years in some subjects
- There are additional signs suggesting potential RPE engraftment in the area of implantation, particularly subretinal hyper-reflective areas seen on OCT both in human subjects and in pigs; in the pigs this correlated with presence of transplanted cells on histology
- New or worsening ERMs were observed in 13/15 subjects in cohorts 1-4, most were mild to moderate in severity. One required intervention and the ERM was peeled 10 weeks post transplant with full recovery
- There was one case of retinal detachment 2 weeks post-op, unknown whether a result of surgical procedure, implanted cells, or a combination of events

Summary (II)

- In general, subretinal transplantation of OpRegen appears well tolerated to date and there are signs indicative of improved retinal structure in the treated areas in some cases. This requires additional follow-up and observation
- Cohort 4 is ongoing, treating subjects with better vision, smaller areas of GA, with a known history of recent progression
- Alternative methods of surgical delivery are under consideration
- Exploration of suprachoidal route of administration for subretinal injection using the FDA 510K cleared Orbit Subretinal Delivery System (SDS) will begin shortly



Thank you!

