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# PROMISING UPCOMING TRIALS FOR PATIENTS WITH GEOGRAPHIC ATROPHY

CALIFORNIA RETINA CONSULTANTS is excited to announce three new trials for the treatment of geographic atrophy (GA). While there are currently no FDA-approved therapies for treating GA, there are still many potential therapies under clinical trial consideration which aim to slow the progression of this disease. The CHROMA/SPECTRI trials, Ionis Pharmaceuticals and Apellis Pharmaceuticals have engineered pharmacological (drug) therapies targeting different components of the complement system, which is believed to play an important role in pathogenesis of AMD. Ionis is targeting another protein in the alternative pathway while Apellis has developed a therapy that targets all three pathways (Classical, Lectin, and Alternative pathways) within the complement system. A third company, Astellas Pharma, is working to treat GA with stem cells, similar to an ongoing study at our Santa Barbara location with Regenerative Patch Technologies (see page 3). Another GA trial sponsored by Genentech is ongoing as well at CRC.

Ionis Pharmaceuticals has developed a self-administered subcutaneous injection of a mRNA antisense inhibitor of complement factor B. The antisense mRNA binds to the mRNA coding for complement factor B resulting in its degradation. The subsequent factor B protein is not produced, and the complement pathway cannot continue. The inflammation and tissue degradation associated with AMD should decrease in response.

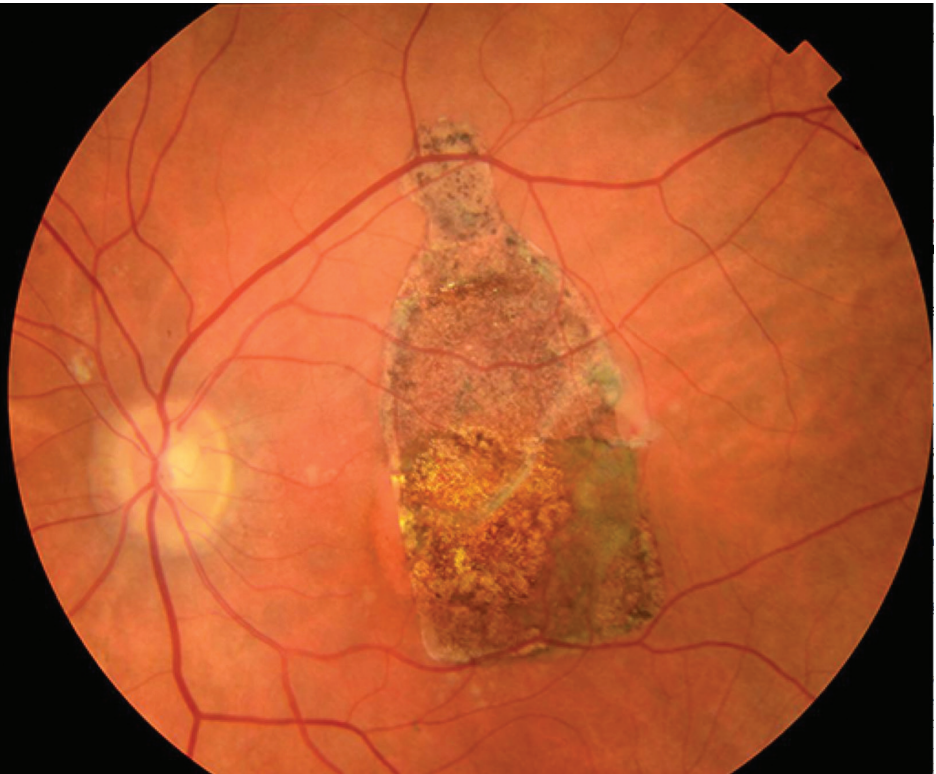
Apellis pharmaceuticals' APL-2 targets Complement protein C3 which is shared by each pathway in the complement system and which may potentially reduce the rate of retinal cell death and atrophic lesion size which will benefit patients regardless of specific complement pathway.

Astellas Institute for Regenerative Medicine (AIRM) brings us a phase I/II trial involving the sub-retinal implantation of human embryonic stem cell-derived retinal pigmented epithelial. This therapy hopes to restore areas of RPE loss before the death of their overlying photoreceptors hopefully preventing progressive vision loss in patients.

While two sponsors have confirmed CRC as a site for their upcoming studies, we are still trying to get approval to bring the third trial to CRC. CRC hopes to enroll all interested, qualified patients with geographic atrophy in one of these trials when they become available. Please feel free to call or email the Santa Barbara study department at (805) 963-1648 with any questions or speak to your physician at your next appointment about treatment options. ■

CALIFORNIA RETINA RESEARCH FOUNDATION

525 E. Micheltorena Street  
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Imaging of the RPT tissue engineered implant  
inside a patient's retina 90 days after surgery.  
See story on page 3.



# InsideRetina

VOLUME I, 2018



CRC's Westlake staff: Rhiannon Townley-back office tech,  
Eslyher Pantoja Oxnard/WLV Office Manager, Nathan Steinle,  
MD, Elaine Fuentes-receptionist, and Tzitzireri Velasquez-back  
office tech.

## CLINIC OPENS IN WESTLAKE

California Retina Consultants is excited to announce our expansion to Westlake Village, California. The new location is 4353 Park Terrace Drive, Suite #150. The demand for quality care in Westlake has been growing and CRC is delighted to serve patients in this region as well as surrounding areas. The clinic opened to patients on February 21, 2018, and is currently operating one-day-per-week. The Westlake Village location is also more accessible for patients who live slightly farther inland and would otherwise need to travel a longer distance to our Oxnard office. As the number of patients served in Westlake Village grows, the clinic will begin operating more frequently, with plans to eventually find a more permanent location. ■



Dr. Avery has had a profound impact on the retina industry, from his medical practice and innovative research to his surgical skills and patient care. With his appointment to the American Society of Retinal Specialists, he will now have a voice in shaping administrative issues, policies and educational opportunities.

regulatory burden that tends to come from Washington. Dr. Avery has vast experience running a solo practice (which later grew to become California Retina Consultants), and he is passionate about helping other groups around the country navigate this process.

Dr. Avery also continues to be the co-medical editor of *Retina Today*, a highly specialized publication that delivers the latest research and clinical developments to a large population of retinal doctors worldwide. ■

## DR. ROBERT AVERY ELECTED TO AMERICAN SOCIETY OF RETINA SPECIALISTS BOARD

CALIFORNIA RETINA RESEARCH FOUNDATION congratulates Dr. Robert Avery on his appointment to the board of directors of the American Society of Retina Specialists (ASRS), the largest association of retina specialists in the world. In this role, Dr. Avery will be involved in organizing the annual practice management meeting, where hundreds of physicians share the latest research, clinical information, and critical issues facing retina practices today. These conferences are instrumental in shaping procedures and policies.

In addition to the annual meetings, Dr. Avery will help draft the society's responses to rogue insurance companies when policies are not in patients' best interests. He and the society advocate on behalf of retina specialists and ophthalmologists, addressing Medicare and Medicaid when necessary. Dr. Avery hopes that he will be able to protect practitioners from the overwhelming

# STUDY DEPARTMENT STAFF UPDATE

**TWO OF OUR OWN ARE OFF TO MEDICAL SCHOOL!** Clinical Research Coordinators John McDermott and Kevin Card will be leaving CRC this summer to start medical school.

John will depart in July and head to UCSD while Kevin, who has already left, prepares to study at the University of Hawaii. Kevin began his time with CRC as an intern and advanced to part-time employee and then to full-time research coordinator. John joined CRC one year ago and became an integral part of the research department so quickly that many may have thought he was here for years. Kevin and John epitomize what a CRC coordinator should be, and we are sure that they will both make excellent doctors one day (maybe they will even end up coming back to CRC as physicians!).

In order to partially fill this gap in the research department, CRC has tapped Kate McKee from the clinic to step in and help Gina make sure the study department continues to run smoothly. Kate joined the clinic at CRC one year ago and has already distinguished herself as an invaluable part of the CRC team as both a FA tech/phlebotomist and a scribing expert. CRC will miss Kevin and John and we wish them well in all future endeavors. ■



CLOCKWISE FROM  
TOP LEFT: John  
McDermott, Kevin  
Card, and Kate  
McKee



Research coordinator Gina Hong  
assists with patient care on last  
year's medical mission to Port-au-  
Prince, Haiti. The team will return  
and expand services in the future.

## CRC PLANS RETURN TRIP TO HAITI

CALIFORNIA RETINA RESEARCH FOUNDATION (CRRF), in conjunction with Surgical Eye Expeditions (SEE) International sponsored two CRC team members, Dr. Dante Pieramici and senior clinical research coordinator Gina Hong, to go to Haiti last year to provide retinal care to patients in Port-au-Prince, as there is only one retinal doctor on the entire island! Dr. Pieramici and Gina were able to provide sight-saving therapies to dozens of people and the trip was so successful that they have been asked to return; both are preparing for another SEE International humanitarian medical expedition to Haiti sometime in 2018.

While the mission for the return trip is to provide more medical care to Haiti's underserved sight-impaired residents, the CRC team also wants to help Haiti build a more stable retina infrastructure by providing further training to Port-au-Prince's sole ophthalmologist, Dr. Reginald Taverne and ophthalmology residents in training at Hospital Universitaire de L'Universite d'Etat d'Haiti (HUEH). Additionally, they are hoping to utilize a new Artificial Intelligence (AI) program on local residents. For the past several months, CRC and CRRF have been working closely with Dr. Kang Zhang and Daniel Kermany from the Shiley Eye Institute at UCSD to test their machine learning algorithm which is designed to determine a basic retinal diagnosis by processing a retinal scan (SD-OCT) image of a patient's retina. The team is hoping that this technology will eventually allow more patients to be effectively evaluated and triaged, especially in countries where there is not enough medical staff and resources to meet the population's needs. Dr. Pieramici and Gina also plan to visit Cap-Haitien to assess viability of bringing AI to that site as well.

Blindness is still an underlying cause of poverty in developing countries and it is estimated that 80% of cases are either avoidable or treatable. By partnering with SEE International and collaborating with Dr. Zhang, CRRF and CRC are making significant strides to offer ophthalmic diagnostic and therapeutic services to developing populations and to help restore sight around the world. ■

# FDA APPROVES NEW THERAPY FOR LEBER'S CONGENITAL AMAUROSIS

*Marking First Gene Therapy Ever Approved for Ophthalmic Conditions*

**THERE IS HOPE FOR PATIENTS** suffering from retinitis pigmentosa (RP) caused by a particular genetic mutation. Spark Therapeutics is now offering a new treatment that may significantly reduce the vision loss associated with this disease. Until recently, RP was an untreatable condition that would eventually lead to varying degrees of vision loss. However, this past December, a novel therapy called Luxterna was approved by the FDA for RP and Leber Congenital Amaurosis (LCA). The novelty of this therapy is actually two-fold as it's the first FDA approved therapy for a very specific type of RP, and also the first gene therapy approved for any ophthalmic condition.

RP can be caused by mutations to a variety of genes, though mutations in the RPE65 gene are the most widely studied in the scientific literature. While we know many patients suffering from these diseases have been desperately seeking any form of therapy for years, Luxterna will only be available for those patients who suffer from the disease due to a functional bi-allelic mutation in their RPE65 gene, which represents only a small fraction of affected patients. This means that they must have defective copies of the gene passed down from both parents. While this may exclude most people who suffer from RP, one bit of good news is that Spark Therapeutics, the manufacturer of

Luxterna, is offering free genetic testing of the RPE65 gene to determine if patients qualify for the treatment. The test can be conducted through a blood draw or saliva collection. If a patient qualifies for Luxterna, Spark Therapeutics will work with patients' insurance companies on a case-by-case basis to try and make this treatment affordable. Without insurance, the cost is a whopping \$435,000 per eye, clearly making it unrealistic. For those suffering from RP of LCA without bi-allelic RPE65 mutations, do not give up hope; research is ongoing and California Retina Consultants and the California Retina Research Foundation will announce breakthroughs as they become available.

More information about Luxterna can be found on the official website at <https://luxterna.com/> or on the official FDA website at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm589467.htm> ■

## REGENERATIVE PATCH TECHNOLOGIES RELEASES EARLY STUDY RESULTS FOR DRY AMD

**YOU MAY HAVE READ** in previous issues of *Inside Retina* that CRC has been participating in a cutting edge stem-cell-based study for dry AMD in conjunction with Regenerative Patch Technologies (RPT). CRC is not only participating, but is the primary enroller for the study and we are excited to report that RPT has recently published the initial findings from the first five patients as the cover story in *Science Translational Medicine*. While it is important to stress that these are *very preliminary* findings, much more work is needed, and this may take many years of development.

RPT reports that they found potential anatomical improvements in a few of the treated eyes and that transplanted cells may have integrated with photoreceptors, the cells responsible for initiating a visual cascade in response to a light stimulus. Additionally, of the five subjects assessed in the initial report, none of the implanted eyes showed progression of vision loss. One subject had a visual acuity improvement of 17 letters (about 3 lines on an eye chart) in their treated eye and three subjects had no change in vision in their treated eyes; two of the subjects also had improved fixation. One subject did not receive the patch due to complications with the insertion procedure; no obvious evidence of safety issues with the treatment was reported in this article, but much more data needs to be evaluated.

RPT's novel therapy entails seeding embryonic stem cells on a proprietary membrane, differentiating them into retinal pig-

ment epithelial (RPE) cells, and inserting the whole unit into the subretinal space. The hope is that the implant will replace RPE cells that have died due to progression of the dry AMD disease. RPE cells are critical for photoreceptor health as they collect and recycle cellular debris produced by photoreceptors during the propagation of the visual cycle. Without RPE cells, debris ends up collecting around the photoreceptors which then die from toxicity. As photoreceptors are actually part of the central nervous system (like the brain and spinal cord), once they are lost, current medical technology cannot regrow or replace them. Thus, it is critical to keep these cells alive.

Currently, there is no FDA approved therapy for treating dry AMD, so trials like this one are very important to thousands of people suffering from this disease. While CRC is currently still enrolling a few subjects in this groundbreaking study in their Santa Barbara office, subjects in other locations are eligible (and encouraged) to participate if they do not mind making the drive for all visits (transportation costs will be fully covered by the study). Please contact the research department at (805) 963-1648 with any questions.

Initial results of the clinical trial were published online in the journal *Science Translational Medicine*. A URL where the results can be found is: (<http://stm.sciencemag.org/content/10/435/eaao4097>).

See diagram on page 6. ■

## EYE SIGHTINGS

**DR. ALESSANDRO CASTELLARIN** will present at the Genentech Advisory Board in Los Angeles and has attended the Aspen Retinal Detachment Society meeting.

**DR. DILSHER DHOOT** presented at the Hawaiian Eye Meeting in Maui, Vitreous Buckle Society in Miami, AAO in New Orleans and to residents and fellows at UCLA and USC.

**DR. DANTE PIERAMICI** presented select novel CRRF research programs at the Cottage Hospital/ UCSB Research Symposium. He also served as visiting professor at Doheny Eye Institute, presenting on *Evolving Imaging and Treatment Modalities for Retinal Diseases* and attended the Macula Society in Beverly Hills. In March, Dr. Pieramici traveled to Dallas to serve on the Executive and Surgical Committees for the Genentech Port Delivery System conference. In May, he presented research at ARVO in Hawaii where he also co-hosted, with Dr. Steinle, the third Retina Believe it or Not Case Presentation Symposium. While in Hawaii, Dr. Pieramici participated on several advisory boards including Novartis, Genentech, Allegro Ophthalmics, and Bausch and Lomb.

**DR. NATHAN STEINLE** has presented so far this year at the national Hawaii Eye meeting in Maui as well as the national Vision Expo meeting in New York City. He also gave presentations in Houston, Oregon, St. Louis, Honolulu, Colorado, Manhattan Beach, and at the Vit Buckle Society in Miami. In the next few weeks, Dr. Steinle and Dr. Dhoot have been invited to give international presentations in Dubai, Abu Dhabi, and Kuwait.

**DR. ROBERT AVERY** was an invited guest speaker at the Aspen Retinal Detachment Society, and also presented research and/or attended advisory boards at the AAO in New Orleans, the Hawaiian Eye meeting in Maui, the Macula Society in LA, and ARVO in Honolulu. ■



## DRS. STEINLE AND DHOOT ELECTED INTO RETINA HONOR SOCIETY

California Retina Consultants is pleased to announce that Drs. Steinle and Dhoot were

recently elected into The Retina Society, an esteemed, merit-based honor society for retina physicians. For the past fifty years, the society has aimed to promote international collaboration in clinical and basic science research in order to further patient care. Each year, only a handful of retina specialists worldwide are granted the honor of joining the organization. Dr. Pieramici is also a longstanding member of the respected honor society. Drs. Steinle, Dhoot, and Pieramici will plan to present research findings from California Retina Consultants at upcoming Retina Society meetings in San Francisco and London. ■

## California Retina Research Foundation

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