The Retinal Consultants Update

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"All Retina All the Time"

Anti-PDGF Combination Agent More Effective Than Ranibizumab Monotherapy for Wet AMD

Retinal Consultants Contribute to Promising Phase 2b Study

The anti-platelet derived growth factor (PDGF) combination agent Fovista (Ophthotech Corp.) showed statistically significant superior efficacy over ranibizumab (Lucentis, Genentech) monotherapy for the treatment of wet AMD, according to the results of a phase 2b study, which were recently reported in an Ophthotech release.

The prospective, randomized, controlled phase 2b study included 449 patients with wet AMD. Participants were randomized to receive 1 of the following treatment regimens administered every 4 weeks for 24 weeks: 0.3 mg Fovista in combination with 0.5 mg ranibizumab, 1.5 mg Fovista in combination with 0.5 mg ranibizumab, or sham in combination with 0.5 mg ranibizumab. The study's primary efficacy endpoint was the mean change in visual acuity from baseline to 24 weeks.

At 24 weeks, patients who received the combination of 1.5 mg Fovista and ranibizumab gained a mean of 10.6 letters of vision on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, compared with 6.5 letters for patients who received ranibizumab monotherapy (P = .019), representing a 62% additional benefit. Enhanced visual outcomes of anti-PDGF combination therapy as compared with ranibizumab monotherapy were shown at every monthly time point. Additionally, the relative magnitude of visual benefit continued to increase over time, with the visual benefit of anti-PDGF combination therapy greater at 6 months than at 3 months.

The benefit of Fovista combination therapy compared with ranibizumab monotherapy was consistent across all subgroups, including those analyzing baseline vision, lesion size, and the proportion of patients who gained 1, 2, 3, 4, and 5 lines of vision on the ETDRS chart, the news release said. An average absolute benefit of 7.4% over ranibizumab monotherapy was present across all ETDRS lines of vision gain. A relative benefit of 25% over ranibizumab monotherapy was achieved in patients who gained 3 or more lines of vision, with 69% and 178% relative benefit in patients who gained 4 or more and 5 or more lines of vision, respectively. No significant safety issues were observed.

We welcomed our newest associate, David Telander, MD, PhD, to the practice in February 2012. For more about Dr. Telander, see page 2.

"This is a truly remarkable finding for patients with wet AMD," Carmen A. Puliafito, MD, Dean of the Keck School of Medicine at the University of Southern California, said in the news release. "To achieve a 62% relative visual

NEW OFFICE!

ROSEVILLE
5 Medical Plaza Dr. #180
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In February 2012, we opened an office in Roseville that has easy access from Interstate 80 and is conveniently located beside the Sutter Roseville Medical Center. The office provides advanced diagnostic equipment and the capability to perform in-office retina procedures. The office is located on the ground floor and has surface-level parking.

benefit over anti-VEGF monotherapy is extraordinary. The very compelling and robust results of this well-executed study validate PDGF as an important target for wet AMD and set the stage for a new era of combination therapy via coformulation or fixed-combination delivery."

Recently, at the Fifth Congress of the Sociedad Panamericana de Retina y Vitreo in San Jose, Costa Rica, Pravin U. Dugel, MD, of Retinal Consultants of Arizona, discussed the results of a phase 1 study of Ophthotech's anti-PDGF combination agent. In that study, 59% of patients gained 3 lines of vision at week 12 of treatment, and 100% of patients demonstrated significant regression of neovascularization.

"For the first time, in patient after patient, with this combination treatment, we saw something that you do not see with anti-VEGF therapy, which is regression of the neovascular complex," Dr. Dugel said. "The size of the neovascular membrane actually shrinks."

"When you step back and think about angiogenesis and neovascularization, these are very complicated processes, and there are hundreds, if not thousands, of chemical factors involved," Dr. Dugel continued. "So, does it really make sense to inhibit only 1 factor, even if it is the most important factor? It probably doesn't. There is no doubt in my mind that combination treatment will be the way we have a sustainable treatment model [for wet AMD]."

Based on the results of the phase 2b study, Ophthotech plans to expedite the preparation of a phase 3 registration program, the news release said.
from EYEWIRETODAY.COM - 6.13.2012

The Newest Retinal Consultant

David Telander MD, PhD

Dr. Telander grew up in Minnesota and graduated valedictorian from Mayo High School in Rochester, MN. He then received a Bachelor of Arts and Science degree in History and Biology from Stanford University here in California. He returned to Minnesota for a combined M.D./ Ph.D. degree from the University of Minnesota. Dr. Telander stayed in Minnesota for his internship at Hennepin County Medical Center and his ophthalmology residency at the University of Minnesota. There he received teaching and research awards.

Dr. Telander completed his surgical retina fellowship training at UCLA / Jules Stein Eye Institute in Los Angeles. Dr. Telander was intimately involved in numerous clinical trials investigating treatments for age-related macular degeneration and diabetic retinopathy.. He joined UC Davis in Sacramento in 2005, where he taught residents and fellows and continued to study novel ways to treat and prevent AMD, inherited retinal degenerations, and retinal scarring processes related to retinal detachment. He was welcomed as one of the Retinal Consultants in February 2012.

Dr. Telander is Board certified by the American Board of Ophthalmology. He is an active member of multiple professional societies including the Retina Society, theAmerican Academy of Ophthalmology, the Association for Research in Vision and Ophthalmology, CONNECT Network, and the American Society of Retina Specialists. He received the Achievement Award from the American Academy of Ophthalmology for his service. He has authored over 30 papers and many book chapters, and has given national and international talks on retinal disease. He has served as Chair of the Sacramento Vision Walk for the Foundation Fighting Blindness and as Program Director and President of the Sacramento ALTA Ophthalmologic Society.

Dr. Telander loves to provide care for his patients, and he has received recognition for his outstanding care, including the Patient Choice Award, "America's Top Ophthalmologist" and "Compassionate Doctor" awards. He has an active family life, and enjoys outdoor sports including skiing, biking, running, snowboarding and hiking.

Trials

Eligible Patients Sought for Enrollment in Clinical Studies Designed to Assess New Therapies

SAKURA - Santen Pharmaceuticals

Currently corticosteroids are the only drug class approved by the FDA for noninfectious uveitis. Because of the potential side effects of steroid use, the search continues for alternative therapies. In SAKURA, Sirolimus with a proprietary formulation for ocular administration is being tested for the treatment of noninfectious, posterior uveitis. This is a 2 year trial assessing the safety and efficacy of intravitreal injections of sirolimus in 3 different dose arms for active, noninfectious uveitis of the posterior segment. Eligible patients must have at least 1+ vitreous haze and best corrected vision of 20/400 or greater in the study eye. The protocol consists of a 30-day screening phase, a 150-day treatment phase and a follow-up phase through 2 years. Rescue therapy is available in the follow-up phase.

NeuroVision Imaging Trial

This pilot study utilizes curcumin labeling and a retinal imaging system to evaluate the ability to detect beta-amyloid plaques in patients with Alzheimer's Disease. The trial is 40 days in duration with 3 visits to the office for imaging, exam, vision testing, and blood draws. The ability to detect these beta-amyloid plaques can potentially lead to noninvasive monitoring of Alzheimer's Disease and even early diagnosis leading to earlier intervention. Open enrollment for this trial is limited to subjects with dry macular degeneration and no diagnosis of Alzheimer's disease for the control group.

VIBRANT - Regeneron Pharmaceuticals

VIBRANT is Regeneron's phase III trial for comparing VEGF Trap-Eye to laser for the treatment of treatment naïve macular edema related to branch retinal vein occlusion. In this 1 year trial, subjects are randomized to laser treatment arm or a study drug arm where VEGF Trap-Eye is administered every 4 weeks and then every 8 weeks beginning at week 24. Patients are seen every 4 weeks for 1 year and there is rescue therapy available. Eligible patients must have best corrected vision in the study eye of 20/40-20/320 and may not have a bilateral manifestation of BRVO.

SEE - Alcon

The search continues to develop a new treatment for wet AMD that prolongs the therapeutic effect of the drug and aims to gain additional visual improvement. This Phase I trial compared a new Anti-VEGF molecule to Lucentis for the treatment of wet AMD. This trial is 6 months long and is designed for treatment naïve wet AMD patients. Subjects receive one intravitreal injection of study drug or Lucentis and are seen every 2 weeks for 6 months to evaluate safety and need for rescue therapy. Patients must have a best-corrected vision between 20/40 and20/200 and a central subfield thickness on SD-OCT of greater than 340 microns.

MATISSE - Quark Pharmaceuticals

This trial evaluates the safety, tolerability and efficacy of a novel intravitreal drug in varying doses, both alone or in combination with Lucentis, to treat diabetic macular edema. Eligible patients must have best-corrected vision in the study eye of 20/40-20/200 and a central subfield thickness on SD-OCT of greater than 340 microns. The trial is 6 months long with monthly intravitreal treatments.

Pfizer Geographic Atrophy Trial

(coming soon)

There are currently no approved therapies for dry macular degeneration. The dry form of AMD affects 90% of those suffering from age-related macular degeneration. This new trial will evaluate the efficacy, safety and tolerability of a novel drug to treat those with dry AMD. Patients will undergo a screening phase, treatment period and observational period in this 15-month trial. The drug is administered systemically, through a 30 minute intravenous infusion. Subjects will be evaluated by routine blood draws, exams, vision checks and periodic MRIs. Eligible patients must be between 60-90 years of age, have a well-demarcated are of geographic atrophy secondary to dry AMD, and best-corrected vision in the study of 20/80 or better.

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Upcoming Events

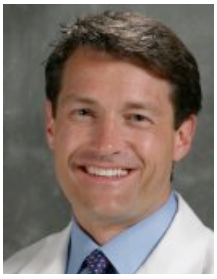
Save the Date for RETINA UPDATE 2012

The Retina Update 2012 meeting will be held on Sunday, September 16, 2012, at the Crocker Art Museum from 10 a.m. to 3 p.m. Lunch will be served. In addition to presentations by the retina faculty, we will also have presentations by our invited guest speakers, Anthony Aldave, MD, from UCLA who will be speaking on "Cataract Surgery in the Eye with Corneal Pathology: Recognition, Avoidance and Management" and Nisha Acharya, MD, MS, from UCSF, who will be speaking on "Old and New Therapeutics for Ocular Inflammatory Disease."

As always, registration for the meeting is free of charge. Meeting attendees are invited to bring a guest to enjoy complimentary admission to the exhibits at the newly renovated and expanded Crocker Art Museum. Space is limited.

Register online at www.retinaupdate.com

RU2012 Featured Guest Speakers



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