Control/Tracking Number: 10-LB-8576-ARVO
Activity: Late Breaker
Current Date/Time: 3/3/2010 12:41:32 PM

DA VINCI: DME And VEGF Trap-Eye: INvestigation of Clinical Impact: Phase 2 study in patients with Diabetic Macular Edema (DME)

Author Block: *J.C. Major, Jr., D.M. Brown, DA VINCI Study Group*. Retina Consultants of Houston, Houston, TX.

Abstract: PURPOSE
VEGF Trap-Eye (VTE) is a recombinant fusion protein consisting of VEGF binding domains of human VEGF receptors 1 and 2 fused to the Fc domain of human IgG1. This phase 2 study assesses the efficacy and safety of intravitreal VTE vs. laser photocoagulation in DME at the 24-week primary endpoint.
METHODS
DA VINCI is a multi-center, randomized, active-controlled Phase 2 clinical study, designed to assess safety and efficacy of 4 dose/dose intervals of VTE in comparison to laser photocoagulation. 221 patients were randomized (219 treated) to 1 of the following treatment arms: 0.5mg q4wks, 2mg q4wks, 2mg q8wks, 2mg prn or laser photocoagulation. The primary endpoint is the mean change from baseline in BCVA at week 24. Secondary endpoints include changes in retinal thickness (CRT) on OCT and central retinal sensitivity. Central retinal sensitivity was measured using the Nidek MP-1 microperimeter with values corresponding to the OCT central subfield.
RESULTS
At 6 months, the mean change in BCVA for each VTE arm ranged from +8.5 to +11.4 letters and was statistically significantly better than the mean change in BCVA in the laser arm (+2.5 letters; $p<0.01$). No significant difference was noted among the VTE arms. Anatomical effects (mean change in CRT) for each VTE arm ranged from -127µm to -195µm and were significantly greater than the mean change in CRT for the laser arm (-68µm; $p<0.01$). VTE arms had a mean gain in central retinal sensitivity ranging from 1.5 to 4.1dB, while the laser arm had a mean decrease of -0.4dB. VTE was generally well-tolerated, and adverse events (AEs) reported were those typically associated with intravitreal injections or underlying disease. There were two cases of endophthalmitis, one culture negative and one positive for Staphylococcus epidermidis. The most frequent AEs reported in the VTE arm include conjunctival hemorrhage, eye pain, floaters, ocular hyperemia, and increased IOP.
CONCLUSION
In this patient population at the 24-week primary endpoint, intravitreal VTE was generally well tolerated and produced significant improvements from baseline in visual acuity and retinal thickness and a trend toward improvement in central retinal sensitivity as compared to laser photocoagulation.
:

Author Disclosure Information: **J.C. Major, Jr.**, Alcon, Alimera, Allergan, CoMentis, Genentech, Jerini, NeoVista, Neurotech, Novartis, Othera, Oxigene, Pfizer, Regeneron; **D.M. Brown**, alcon, Alimera, Allergan, CoMentis, Genentech, Jerini, NeoVista, Neurotech, Novartis, Othera, Oxigene, Pfizer, Regeneron; alcon, Allergan, Carl Zeiss Meditec, Genentech, Heidelberg Engineering, Molecular Partners, NeoVista, Novartis, Ocuus, Regeneron, Stobe

Reviewing Codes (Complete): 183 diabetic retinopathy: clinical research – RE
Presentation Preference (Complete): Paper #1, Poster #2
Keyword (Complete): 499 diabetic retinopathy ; 466 clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials ; 744 vascular endothelial growth factor
Clinical Trial, Newsworthy, & Eligibility (Complete):
***Does the study meet the definition of a clinical trial?**: Yes
: www.clinicaltrials.gov **NCT00789477**
***Newsworthy**: Yes
Public : True
Researchers in Other Disciplines : True
Clinicians : True
*** Eligibility Statement** : Data not available for primary endpoint (24 week) until February 2010

Support (Complete):
***Support** : None

Status: Complete