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Results of a Phase I Study of Intravitreal VEGF Trap in Subjects With Diabetic Macular Edema: The CLEAR-IT DME Study

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Abstract

Purpose:: To determine the safety, tolerability, and bioactivity of a single dose (4.0mg) of intravitreal VEGF Trap in patients with diabetic macular edema (DME).

Methods:: Five patients with DME, foveal thickness ≥ 250µm measured by optical coherence tomography (OCT) and ETDRS best-corrected visual acuity (BCVA) of ≤ 20/40 and ≥ 20/320 were administered a single intravitreal injection of 4 mg VEGF Trap at day 0. Safety assessments included eye examinations, vital signs, and laboratory tests. Measures of bioactivity included changes from baseline in BCVA, centerpoint retinal thickness (CRT), and leakage on fluorescein angiography. Subjects were monitored for 6 weeks following VEGF Trap administration.

Results:: Mean patient age was 65.2 years (range=56-75); 4 were Type 2 diabetics. Mean duration of diabetes prior to treatment was 26 years. All had received prior treatment for DME. No severe ocular or serious systemic adverse events related to study drug were noted. Mean baseline BCVA was 69 letters and mean baseline CRT was 407µm. Four patients had improvements in BCVA, ranging from 6 to 10 letters at 4 weeks post-injection. The mean decrease in centerpoint retinal thickness was 115µm at 4 weeks.

Conclusions:: A single intravitreal dose of VEGF Trap was well-tolerated and led to a reduction in CRT and an improvement in BCVA. Although the number of subjects is small, preliminary evidence for bioactivity of VEGF Trap in patients with DME was detected.

Additional studies are being planned to identify the potential therapeutic role of intravitreal VEGF Trap in DME.

Clinical Trial:: www.clinicaltrials.gov NCT 00320814

Keywords: diabetic retinopathy • macula/fovea • clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials