

## Study Eye Criteria

### Inclusion

- a) VA letter score  $\leq 68$  (approximate Snellen equivalent 20/50) and  $\geq 24$  (approximate Snellen equivalent 20/320)
- b) On clinical exam, definite retinal thickening due to diabetic macular edema involving the center of the macula.
- c) Diabetic macular edema present on OCT within eight days of randomization
- d) Media clarity, pupillary dilation, and individual cooperation sufficient for adequate fundus photographs.

#### **OCT Thresholds**

Cirrus:  $\geq 290\mu\text{m}$  in women and  $\geq 305\mu\text{m}$  in men  
Spectralis:  $\geq 305\mu\text{m}$  in women and  $\geq 320\mu\text{m}$  in men

### Exclusion

- e) Macular edema is considered to be due to a cause other than DME.
- f) An ocular condition is present such that, in the opinion of the investigator, visual acuity loss would not improve from resolution of macular edema (e.g., foveal atrophy, pigment abnormalities, dense subfoveal hard exudates, non-retinal condition).
- g) An ocular condition (other than DR) is present that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (e.g., vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, etc.).
- h) Substantial cataract that, in the opinion of the investigator, is likely to be decreasing visual acuity by three lines or more (i.e., cataract would be reducing acuity to 20/40 or worse if eye was otherwise normal).
- i) History anti-VEGF treatment for DME within the prior 12 months or any other treatment for DME in the prior 4 months.
- j) History of PRP within prior 4 months or anticipated need for PRP in the six months following randomization.
- k) History of anti-VEGF treatment for a disease other than DME in the past 12 months.
- l) History of major ocular surgery within prior 4 months or anticipated within the next 6 months.
- m) History of YAG capsulotomy performed within two months prior to randomization.
- n) Aphakia.
- o) Exam evidence of external ocular infection, including conjunctivitis, chalazion, or significant blepharitis.
- p) Evidence of uncontrolled glaucoma (IOP must be  $< 30$ , with no more than 1 topical glaucoma med, and no documented glaucomatous field loss).

#### **Major Ocular Surgery includes:**

- Vitrectomy
- Cataract extraction
- Scleral buckle
- Any intraocular surgery