

Combined Efficacy of Intravitreal Ranibizumab in Two Phase III Studies of Choroidal Neovascularization Secondary to Age-related Macular Degeneration

Anat Loewenstein, MD (Tel Aviv, Israel),* MARINA and ANCHOR Study Group

PURPOSE

Is Ranibizumab effective in the treatment of CNV secondary to AMD?

METHODS

Ranibizumab has been tested in two Phase III, randomized, multicenter, double-masked, controlled studies of patients with minimally classic or occult lesions (MARINA study, n=716) and predominantly classic lesions (ANCHOR study, n=423). Two year results are available for MARINA, and one-year results are available for ANCHOR.

RESULTS

The MARINA & ANCHOR Phase III studies met the 10 efficacy endpoints, demonstrating that both ranibizumab doses were superior to sham & verteporfin PDT in maintaining & improving visual acuity (VA). In both studies, 94-95% of patients treated with ranibizumab 0.3mg & 95-96% of patients treated with 0.5mg lost <15 letters at month 12 ($p < 0.0001$), vs 62% in the sham group (MARINA) & 64% in the PDT group (ANCHOR). This was independent of lesion type, size or baseline VA. Substantial mean improvements in VA over baseline were seen after the first ranibizumab treatment (both studies & doses) & maintained. In contrast a mean decline of 10 letters was observed in controls. More ranibizumab patients (25-40%) (both studies & doses) gained >15 letters at month 12 Vs controls (5-6%). Ranibizumab treated eyes showed stabilization of lesion size, reduction in leakage area by 2 disc areas (DA) Vs a 2 DA increase in lesion size & a 0.3-0.7 DA increase in leakage area in the control groups.

CONCLUSION

As shown in two independent Phase III studies, monthly ranibizumab 0.3mg or 0.5mg administered intravitreally to patients with neovascular AMD produced rapid improvements in vision that were sustained for up to 2 years. The improvements in vision-related parameters are consistent across all CNV lesion types and patient subgroups.

* Financial interest disclosed