

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

Paolo Lanzetta, MD (Udine, Italy),\* MARINA and ANCHOR Study Groups

### **PURPOSE**

To examine the consistency of safety across two studies of ranibizumab in three populations of patients with different subtypes of choroidal neovascular lesions: predominantly classic, minimally classic and occult lesions with no classic component.

### **METHODS**

Ranibizumab has been tested in 2 Phase III, randomized, multicenter, double-masked, controlled studies of patients with minimally classic or occult lesions (MARINA, n=716) and predominantly classic lesions (ANCHOR, n=423). 2-year results are available for MARINA, and 1-year results are available for ANCHOR. In total, 754 patients received monthly intravitreal ranibizumab 0.3mg or 0.5mg in the 2 studies, with more than 9200 ranibizumab injections being performed in the first 12 months of both studies (ANCHOR and MARINA). The mean patient age was 77 years, and 97% of patients were Caucasian. Patient enrollment was not excluded based on evidence or history of severe cardiac disease.

### **RESULTS**

Five ranibizumab patients experienced presumed endophthalmitis across both studies. At the Month-12 time point none of these five patients lost >15 letters of best corrected visual acuity. The per-injection rate of serious ocular adverse events (AEs) was very low (0.12%) for each dose group. In a combined analysis of the two Phase III studies, severe ocular AEs were experienced by <7.5% of ranibizumab patients, compared to 5.6% of verteporfin patients (ANCHOR) and 10.2% of sham-treated patients (MARINA). There was no significant imbalance in the incidence of systemic serious AEs between ranibizumab and control groups in either study. The incidence of cardiovascular adverse events was at a similarly low rate in all treatment groups including sham. No deaths in either study were attributed to ranibizumab. 2-year data from MARINA show that ranibizumab continues to be well tolerated.

### **CONCLUSION**

As shown in these two independent Phase III studies, monthly intravitreal ranibizumab 0.3mg or 0.5mg in patients with neovascular AMD was well tolerated. Ocular serious adverse events were uncommon in both studies. There was no imbalance in the incidence of systemic severe adverse events among the control and treatment groups in either study.

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