

## Two-year Efficacy and Safety Results from the MARINA Study

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### PURPOSE

The MARINA study is a 2-year, Phase III, multicenter, randomized, double-masked, sham injection-controlled study designed to evaluate the efficacy and safety of monthly intravitreal injections of ranibizumab used as a treatment for minimally classic or occult choroidal neovascularization secondary to age-related macular degeneration.

### METHODS

A total of 716 participants were randomized in a 1:1:1 ratio to receive monthly intravitreal ranibizumab 0.3mg (n= 238), 0.5mg (n= 240), or sham injection (n= 238) for 24 months. Efficacy endpoints at Month-24 compared with baseline included: proportion of patients losing <15 letters of BCVA, gaining >15 letters of BCVA; proportion of patients with BCVA of 20/200 or worse; mean change of BCVA; mean change in selected sub-scales of VFQ-25; mean change in total area of CNV and mean change in total area of leakage from CNV. Safety assessments included ocular and non ocular adverse events, ocular assessments, laboratory evaluations and vital signs.

### RESULTS

Of the 716 originally randomized patients, 683 patients (95%) continued into the second year of treatment. 92% and 90%, of the patients receiving ranibizumab 0.3mg or 0.5mg, respectively, lost <15 letters at 2 years, compared to 52.9% in the sham-injection treatment group (p<0.0001). Patients treated with ranibizumab 0.3mg or 0.5mg showed a mean improvement in BCVA of 5.4 or 6.6 letters over baseline at Month-24, while sham patients experienced a mean loss of 14.9 letters. 26.1% and 33.3% of ranibizumab 0.3mg and 0.5mg patients gained >15 letters at 2 years, compared to 3.8% of patients in the sham-treatment group (p<0.0001). The overall incidences of serious ocular adverse events (8.4%, 8.8% and 7.2%), serious systemic adverse events (34.5%, 31.8% and 30.9%) and deaths (2.1%, 2.5% and 2.5%) were similar for the ranibizumab 0.3mg, 0.5mg and sham groups respectively.

### CONCLUSION

Ranibizumab 0.3mg or 0.5mg produced rapid improvements in BCVA that are maintained for at least 2 years, with the benefit of ranibizumab over sham increasing over time. In addition Ranibizumab treatment prevented growth of the CNV lesions, decreased the area of leakage, and is well tolerated, with no imbalances in ocular or non-ocular adverse events between control and treatment groups.