

Ranibizumab (Lucentis™) Vision-specific Quality of Life through 24 Months in Neovascular AMD Subjects in MARINA: A Phase III Clinical Trial

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PURPOSE

To examine the effects of ranibizumab (Lucentis) on patient-reported vision-specific QoL using the NEI-VFQ 25 through 24 months in MARINA: a Phase III randomized trial of subjects with subfoveal choroidal neovascularization (CNV) with minimally classic lesions or occult lesions with no classic component and recent disease progression due to age-related macular degeneration (AMD).

METHODS

The NEI-VFQ 25 was administered to subjects with CNV due to AMD with minimally classic or occult lesions at baseline and months 1, 2, 3, 6, 9, 12, 18, and 24. Subjects were randomized 1:1:1 to sham, 0.3 mg, and 0.5 mg ranibizumab. QoL was assessed by change in mean score from baseline at months 12 and 24 for each NEI-VFQ 25 subscale with last observation carried forward for missing values. Results reported for month 12 below will be updated through 24 months at presentation. The NEI-VFQ 25 subscales are scored from 0-100; a positive difference represents improved functioning or reduced dependency. Pre-specified subscales included near activities, distance activities, and dependency.

RESULTS

Of 716 subjects (238 sham, 238 0.3 mg, 240 0.5 mg) at baseline, 663 (212 sham, 225 0.3 mg, 226 0.5 mg) at 12 mos. had mean overall score changes of -2.8, +5.2 ($P < .0001$ vs sham), and +5.6 ($P < .0001$ vs sham). Ranibizumab subjects had mean changes of +9.9 for near activities, +6.9 for distance activities, and +5.2 for dependency, vs -2.6, -5.9, and -4.7 respectively for sham ($P < .0001$, each dose vs sham). Proportions of subjects gaining ≥ 10 points from baseline were higher for ranibizumab for overall score ($P < .0001$, each dose vs sham) and for each prespecified subscale ($P < .0001$, each dose vs sham).

TABLE:

Proportion (%) of subjects with ≥ 10 pt gain in NEI-VFQ 25 score, month 12 Sham n=238 0.3 mg ranibizumab n=238 0.5 mg ranibizumab n=240 Overall VFQ 11 32 33 Near activities 21 44 44 Distance activities 16 38 40 Dependency 14 29 33

CONCLUSION

The MARINA Trial is the first to report improvement in vision-specific QoL following pharmacologic intervention for neovascular AMD. A greater proportion of ranibizumab treated subjects reported clinically relevant improvements (≥ 10 pt) in vision-specific QoL. These results support visual acuity outcomes favoring ranibizumab.

* Financial interest disclosed