

## Vision-specific Quality of Life at 12 Months in Predominantly Classic Neovascular AMD in ANCHOR: A Phase III Trial of Ranibizumab and Verteporfin PDT

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### PURPOSE

To examine the effects of ranibizumab (Lucentis™) on patient-reported vision-specific quality of life (QoL) using the NEI-VFQ 25 through 12 months in subjects with predominantly classic subfoveal choroidal neovascularization (CNV) due to age-related macular degeneration (AMD) in ANCHOR, a phase III randomized, double-masked trial of ranibizumab and verteporfin photodynamic therapy (PDT).

### METHODS

The NEI-VFQ 25 was administered to subjects with predominantly classic subfoveal CNV due to AMD in ANCHOR at baseline and months 1, 2, 3, 6, 9, and 12. Subjects were randomized 1:1:1 to verteporfin PDT, 0.3 mg, and 0.5 mg ranibizumab. QoL was assessed by change in mean score from baseline at month 12 for each of the NEI-VFQ 25 subscales with last observation carried forward for missing values. The NEI-VFQ 25 subscales are scored from 0-100 and a positive difference represents improved functioning or reduced dependency. Near activities, distance activities and vision-related dependency were prespecified as secondary efficacy endpoints.

### RESULTS

418 subjects (142 verteporfin PDT, 137 0.3 mg, 139 0.5 mg) at baseline and 379 subjects (126 verteporfin PDT, 125 0.3 mg, 128 0.5 mg) at month 12 were studied. Mean changes in the overall NEI-VFQ composite score from baseline were +2.2 for verteporfin PDT, +5.9 for 0.3 mg ( $P=0.0025$  vs. verteporfin PDT) and +8.1 for 0.5 mg ( $<0.0001$  vs. verteporfin PDT). Mean changes in the near activities subscale from baseline were +3.7 for verteporfin, +6.6 for 0.3 mg ranibizumab ( $P? 0.0932$  vs verteporfin), and +9.1 for 0.5 mg ranibizumab ( $P<0.0093$  vs. verteporfin). Mean changes from baseline in the distance activities subscale were +1.7 for verteporfin PDT, +6.4 for 0.3 mg ranibizumab ( $P? 0.0071$  vs. verteporfin PDT), and +9.3 for 0.5 mg ranibizumab ( $P<0.0001$  vs. Verteporfin PDT). Mean changes from baseline in the vision-related dependency subscale were -1.4 for verteporfin PDT, +7.6 for 0.3 mg ranibizumab, and +8.9 for 0.5 mg ranibizumab ( $P<0.0001$  for each dose group vs. verteporfin PDT).

### CONCLUSION

Ranibizumab treated subjects reported, on average, greater improvements in patient-reported QoL outcomes than verteporfin PDT subjects for prespecified NEI VFQ-25 subscales in ANCHOR. These data are consistent with QoL results in the Phase III MARINA trial of minimally classic or occult lesions and support the visual acuity outcomes at month 12 favoring ranibizumab over verteporfin PDT.

\* Financial interest disclosed