

PIER: Year 1 Results of a Phase IIIB Study of Ranibizumab Efficacy and Safety in Choroidal Neovascularization Due to Age-related Macular Degeneration

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PURPOSE

PIER is a 2-year study of the safety and efficacy of intravitreal injections of 2 different doses (0.3 and 0.5 mg) of ranibizumab (Lucentis™), administered monthly for 3 doses followed by doses every 3 months, compared with sham injections in patients with subfoveal choroidal neovascularization (CNV), with or without classic CNV, secondary to age-related macular degeneration (AMD).

METHODS

In this multicenter, double-masked, controlled trial, patients with neovascular AMD were randomized 1:1:1 to 0.3 mg ranibizumab, 0.5 mg ranibizumab, or sham injections. A total of 10 ranibizumab or sham injections may be administered during the 2-year study period (6 during the first year). In the prespecified primary efficacy analysis at 1 year, the primary endpoint is mean change from baseline in best-corrected ETDRS visual acuity score at 12 months. Changes in CNV lesion morphology are being assessed in all patients using fundus photography and fluorescein angiography. Safety assessments include the incidence and severity of ocular and nonocular adverse events at 12 and 24 months.

RESULTS

Between September 2004 and March 2005, 184 patients were enrolled and randomly assigned to study treatment. At the time of abstract submission, the study was still masked and therefore 1-year efficacy and safety results were not yet available. The 1-year results will be presented at this meeting.

CONCLUSION

Twelve-month efficacy and safety data from the Phase IIIB PIER trial of ranibizumab treatment of subfoveal neovascular AMD will be presented.

* Financial interest disclosed