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Safety and Efficacy of Ranibizumab Treatment in Patients With Neovascular Age-Related Macular Degeneration: 12-Month Results of the SUSTAIN Study

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Footnotes

Commercial Relationships F.G. Holz, Genentech, C; Acucela, C; Pfizer, C; Novartis, C; C. Meyer, Novartis, C; N. Eter, Novartis, C; Novartis, R.

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Abstract

Purpose: : To evaluate the safety and efficacy of individualized ranibizumab treatment over 12 months of patients with neovascular age-related macular degeneration (AMD).

Methods: : In the prospective, multi-center, single-arm SUSTAIN study of 12 months duration, 513 ranibizumab-naïve AMD patients (results reported below) and 18 AMD patients from the ANCHOR study received 3 initial monthly injections of ranibizumab (0.3 mg) and re-treatment with ranibizumab (0.3/0.5 mg; one-third of patients switched to 0.5 mg during the study) in the maintenance phase when they either lost >5 letters in best

retinal thickness (CRT) increased by >100 µm from the lowest prior value measured by optical coherence tomography (OCT). No re-treatment was given when CRT was <225 µm or BCVA ≥79 letters. BCVA and CRT were assessed monthly using Early Treatment for Diabetic Retinopathy Study charts and optical coherence tomography, respectively.

Results: : On average, patients were treated 2.7 times from Months 3 to 11. 21% of patients received no re-treatment in the maintenance phase. Serious adverse events (AEs) in the study eye: retinal hemorrhage (n=2), cataract (n=1), retinal pigment epithelial tear (n=1), reduced visual acuity (n=1), vitreous hemorrhage (n=1). Most frequent non-ocular serious AEs: cardiac failure (n=6), myocardial infarction (n=5). Most frequent non-ocular AEs: nasopharyngitis (n=16), hypertension (n=15). Most frequent ocular AEs: reduced visual acuity (n=95), retinal hemorrhage (n=37), increased intraocular pressure (n=36). Mean change in BCVA from baseline to Months 3 and 12 was +5.8 and +3.6 letters, respectively. Mean change in CRT from baseline to Months 3 and 12 was -101.1 and -91.5 µm, respectively.

Conclusions: : The incidence of AEs was comparable to previous pivotal clinical studies with ranibizumab. The efficacy results suggest that flexible dosing based on VA/OCT-guided re-treatment criteria may stabilize but does not increase BCVA above the levels achieved in the loading phase. Efficacy outcomes were achieved with a low average number of treatments.

Clinical Trial: : www.clinicaltrials.gov NCT00331864

Keywords: age-related macular degeneration • vascular endothelial growth factor • visual acuity