Ranibizumab Improves Acuity in Macular Edema

BY MIRIAM E. TUCKER

VIENNA — Ranibizumab treatment was associated with continuous improvement in best-corrected visual acuity and central retinal thickness over 12 months in a randomized, placebo-controlled study of 151 patients with diabetic macular edema.

The multicenter RESOLVE (Safety and Efficacy of Ranibizumab in Diabetic Macular Edema With Center Involvement) study randomized 51 patients to 6 mg/mL and 51 patients to 10 mg/mL of ranibizumab per intravitreal injection, and 49 patients to sham injections, Dr. Katrin Engelmann said at the annual meeting of the European Association for the Study of Diabetes.

Patients were given three initial monthly injections followed by retreatment based on predefined success or safety criteria. After the first month, the injection volume was doubled if central retinal thickness was greater than 300 mcm or was greater than 225 mcm and the reduction in edema from the previous treatment was less than 50 mcm. Best-corrected visual acuity (BCVA) and optical coherence tomography (OCT) were assessed monthly.

Injection volume was doubled in 65% of the ranibizumab patients (both dose groups combined), compared with 92% of the sham injection group. Rescue laser photocoagulation treatment was required in 9% of the ranibizumab group, compared with 33% of the sham treatment group.

The proportion of patients who gained visual acuity from baseline to month 12 was 90% with ranibizumab, compared with 55% who received sham injections.

The mean BCVA increased and mean OCT decreased continuously over time in the ranibizumab patients. From baseline to month 12 there was a mean gain of 11.8 letters in the 6-mg/mL ranibizumab group, and 8.8 letters with the 10-mg/mL group (a pooled mean gain of 10.3 letters), compared with a loss of 1.4 letters in the sham treatment group, said Dr. Engelmann, of Klinikum Chemnitz GmbH, Saxony, Germany.

The most frequent ocular adverse events were conjunctival hemorrhage (14% sham, 23% ranibizumab) and eye pain (20% and 18%). Serious ocular adverse events occurred in one sham patient and in four ranibizumab patients. Nonocular arterial thromboembolic events occurred in two sham and three ranibizumab (10 mg/mL) patients.

Overall, the profile of ranibizumab in diabetic macular edema as seen in this study was similar to that found in previous randomized controlled studies trials of patients with neovascular age-related macular degeneration, she noted.

Ranibizumab (Lucentis) is marketed in Europe by Novartis and in the United States by Genentech for the treatment of patients with wet age-related macular degeneration. Novartis funded the RESOLVE study. ■