Drugs 2007; 67 (8): 1207-1209
0012-6667/07/0008-1207/$49.95/0

Ranibizumab

A Viewpoint by Steven D. Schwartz

Department of Ophthalmology, Jules Stein Eye Institute, University of California Los Angeles (UCLA), Los Angeles, California, USA

Ranibizumab is the first US FDA-approved therapy for neovascular age-related macular degeneration (AMD) to improve vision for a majority of patients irrespective of lesion type. The results of the ranibizumab clinical trials were overwhelmingly positive, redefining efficacy for the treatment of neovascular AMD. In contrast to other treatments, ranibizumab prevented significant vision loss in >90% of patients who were treated with monthly injections for 2 years.

Results from three ranibizumab clinical trials were included in the biologics licence application filed with the FDA for approval of ranibizumab as a treatment for wet AMD. In the MARINA and ANCHOR trials, ranibizumab-treated patients gained a mean of 7–11 letters on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, while the control groups lost 10–15 letters. More impressively, 33% of ranibizumab-treated patients in the MARINA trial and 41% in the ANCHOR trial actually gained at least 15 letters of vision. In the third trial, PIER, an alternative dosing regimen was evaluated. Patients were injected once a month for three months, followed by one dose every 3 months for a total of six injections. After an initial gain in vision of 4.8 letters at month 3, ranibizumab-treated patients lost 0.2 letters on average by month 12, while the sham group lost 16.3 letters. There was not a significant increase in patients gaining >15 letters compared with the sham group when this treatment regimen was used.

Ranibizumab has a favourable tolerability profile with a very low risk of ocular adverse events. The incidence of non-ocular adverse events, such as myocardial infarction and stroke, have been balanced between the ranibizumab-treated and comparator groups across trials. Recently, an interim safety analysis of the SAILOR expanded access trial revealed a 4-fold greater incidence of stroke for the group treated with the 0.5mg ranibizumab dose compared with those treated with the 0.3mg dose. However, the incidence of stroke (1.2% in the 0.5mg group) was similar to those reported in the MARINA and ANCHOR trials. The FDA has made no indication that any change will be made to the ranibizumab prescribing information at this time.

Ranibizumab has been rapidly adopted by retina practices across the country as the standard of care for first line therapy in treating neovascular AMD. Since the launch of the drug in July 2006, >61 000 patients have been treated with ranibizumab. The cost of ranibizumab is high, but the outcome in terms of visual function saved or regained, and its subsequent impact on improving quality of life, on independent maintenance of activities of daily living, and the overall impact on society make this an important treatment. In the US, ranibizumab is being reimbursed by most insurance companies and Medicare. If a patient has financial difficulties or no insurance, Genentech has programs in place to assist retina practices help patients gain access to ranibizumab. The economic impact of this effective, but relatively expensive drug will continue to be a topic of debate for years to come. ▲