

Bayer seeks EU marketing approval for aflibercept in BRVO

Aflibercept (Eylea, Bayer HealthCare, Berlin, Germany) has been submitted to European regulators for the treatment of macular edema following branch retinal vein occlusion (BRVO), Bayer said in a news release.

Eylea is currently marketed in Europe for the treatment of patients with neovascular age-related macular degeneration and the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion. Bayer is also seeking marketing authorization on Eylea for the treatment of diabetic macular edema.

The submission is based on the positive results from the phase 3 VIBRANT trial, which was a double-masked, randomized, active-controlled study of patients with macular edema secondary to BRVO. In the VIBRANT study, 53% of patients who received aflibercept solution for injection 2 milligram monthly gained at least 15 letters (equivalent to three lines) in best corrected visual acuity from baseline at week 24, the primary endpoint of the study, compared to 27% of patients who received laser, the current standard of care ($P < 0.001$), Bayer said.