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AURIGA 24-MONTH, REAL-WORLD RESULTS FROM TREATMENT-NAÏVE PATIENTS WITH MACULAR EDEMA SECONDARY TO RVO TREATED WITH INTRAVITREAL AFLIBERCEPT IN ITALY

Oral

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Purpose:

AURIGA (NCT03161912) evaluated intravitreal aflibercept (IVT-AFL) treatment of diabetic macular edema or macular edema secondary to retinal vein occlusion (RVO) in routine clinical practice. Important insights into IVT-AFL effectiveness and treatment patterns were obtained across 11 countries. Here, we report real-world, 24-month outcomes for treatment-naïve patients with RVO in Italy.

Methods:

AURIGA was a 24-month, prospective, and multicenter observational study. Eligible patients (aged ≥ 18 years) with treatment-naïve central RVO (CRVO) or branch RVO (BRVO) were treated with IVT-AFL for up to 24 months at their physician's discretion, and according to local regulations. Primary endpoint was visual acuity (VA) change from baseline to Month (M) 12. Secondary endpoints included VA change by M24, central retinal thickness (CRT) change by M12 and M24, and number of IVT-AFL injections by M6, M12, and M24. Statistics were descriptive and no formal hypothesis testing was planned. Systemic and ocular safety were monitored throughout the study.

Results:

In 152 patients (mean age: 66.8 years), mean (95% CI) VA increased from baseline by +12.2 (5.6, 18.8) letters (CRVO) and +10.3 (7.0, 13.6) letters (BRVO) at M12, and +11.8 (5.0, 18.5) letters (CRVO) and +10.4 (6.7, 14.1) letters (BRVO) at M24. From baseline, mean \pm SD CRT decreased by 275 \pm 260 μ m (CRVO) and 163 \pm 149 μ m (BRVO) at M12, and 297 \pm 230 μ m (CRVO) and 157 \pm 166 μ m (BRVO) at M24. Overall, the mean number of IVT-AFL injections was 3.9 \pm 1.2 by M6, 4.8 \pm 2.0 by M12, and 5.7 \pm 3.1 by M24. No cases of retinal vasculitis or intraocular inflammation, including endophthalmitis, were reported.

Conclusions:

AURIGA was the largest study to evaluate IVT-AFL treatment of RVO in routine clinical practice globally. In Italy, treatment-naïve patients with RVO achieved clinically relevant and durable improvements that were maintained over 24 months of IVT-AFL treatment. The safety profile of IVT-AFL was consistent with that observed in previous studies.