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AURIGA 24-month results from treatment-naïve patients with DME treated with intravitreal aflibercept in Italy

Oral

Parravano M.C.*[1], Carnovale Scalzo G.[2], Erba S.[3], Grassi M.O.[4], Allmeier H.[5], Machewitz T.[6], Molina D.[5], Vadalà M.[7]

[1]Department of Ophthalmology, IRCCS-Fondazione Bietti, Rome, Italy, [2]Department of Ophthalmology, University Magna Græcia of Catanzaro, Catanzaro, Italy, [3]ASST Fatebenefratelli Sacco, Oftalmico Hospital, Milan, Italy, [4]Eye Clinic, University of Bari, Bari, Italy, [5]Bayer Consumer Care AG, Basel, Switzerland, [6]Bayer AG, Berlin, Germany, [7]Biomedicine, Neuroscience and Advanced Diagnostic Department, University of Palermo, Palermo, Italy

Purpose:

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

Methods:

AURIGA was a 24-month, prospective, observational study. Eligible patients (aged ≥18 years) with treatment-naïve DME were treated with IVT-AFL for up to 24 months at their physician's discretion and according to local regulations. The primary endpoint was change in visual acuity (VA; Early Treatment Diabetic Retinopathy Study [ETDRS] letters) from baseline to Month (M) 12. Secondary endpoints included change in VA by M24, change in central retinal
thickness (CRT) 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. Safety was monitored throughout the study.

Results:

In 207 patients (mean age, 65.6 years), mean (95% CI) VA improved by +6.3 (3.4, 9.1) letters at M12 and +5.0 (1.8, 8.2) letters at M24 from baseline. Stratified by baseline VA of <35 letters, 35–69 letters, and ≥70 letters, mean VA gains by M24 were +30.5, +2.6, and −1.7 letters, respectively. From baseline, mean±SD CRT decreased by 105±139 µm at M12 and 115±151 µm at M24. Mean±SD number of IVT-AFL injections was 4.1±1.4 by M6, 5.0±2.0 by M12, and 5.6±2.7 by M24. No cases of retinal vasculitis, retinal vascular occlusion, or intraocular inflammation, including endophthalmitis, were reported.

Conclusions:

AURIGA was the largest real-world study to date investigating IVT-AFL treatment of DME. In Italy, treatment-naïve patients achieved clinically relevant and durable improvements after 24 months of treatment, particularly patients with lower baseline VA. The safety profile of IVT-AFL was consistent with that observed in previous studies.