Absence of Safety Signal for Occlusive Retinal Vasculitis with Intravitreal Afibercept Injection

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Purpose:

To examine long-term safety experience with intravitreal afibercept injection for occurrence of occlusive retinal vasculitis (ORV), or retinal artery occlusion (RAO) in the presence of intraocular inflammation (IOI), in light of recent reports of loss of vision associated with ORV in the context of IOI with brolucizumab.

Methods:

Afibercept Phase 3 clinical trials (n=8) and the Global (Post Marketing) Safety Database (GSD) were reviewed to identify IOI events concurrent with RAO or retinal vasculitis. A MedDRA PT search strategy was conducted to identify retinal vasculitis events. As no single term captures ORV events, MedDRA PT terms were used to identify RAO and/or retinal/ocular vasculitis in case reports of IOI. GSD cut-off date was March 31, 2020.

Results:

A review of the afibercept clinical trial database comprised of >3000 patients treated with afibercept found no reports of IOI co-occurring with RAO or retinal vasculitis. In the post-marketing GSD through March 31, 2020, six cases of IOI concurrent with RAO or retinal/ocular vasculitis were identified. Five of these six cases included endophthalmitis in the case description; in four of these five cases, the data suggested that an infectious etiology was the most likely cause. The sixth case involved RAO in the context of temporal arteritis, with IOI following 3 days later. Based on post-marketing exposure of more than 34 million vials of intravitreal afibercept injection sold in >100 countries worldwide, IOI with RAO or retinal/ocular vasculitis was reported at a rate of approximately one out of every six million intravitreal afibercept injection vials sold (<0.00002%). Most cases were associated with endophthalmitis.

Conclusions:

Based on reviews of the afibercept clinical trial database and the post-marketing GSD, ORV events in the context of IOI are not considered a safety concern with use of intravitreal afibercept. This strongly suggests that IOI concurrent with RAO and/or ORV is not a general anti-VEGF class effect.