8/01/2025

Wet AMD Symposium 1

Baseline and Early Treatment Response Variables Associated With Faricimab Durability in Treatment-Naive nAMD: TENAYA/LUCERNE Post Hoc Analyses

- Benjamin Bakall, MD, PhD
- Colin Tan, MBBS, MMed (Ophth), FRCSEd (Ophth)
- Roberto Gallego-Pinazo, MD, PhD
- Adrian Koh, MBBS, Med (Ophth), FRCS (Ed), FAMS
- John Pitcher, MD
- Ming Yang, PhD
- Shriji Patel, MD, MBA
- Philippe Margaron, PhD

Objective: To evaluate baseline and early treatment response variables associated with treatment durability in faricimab-treated patients with neovascular age-related macular degeneration.
Purpose: In the TENAYA/LUCERNE (NCT03823287/NCT03823300) trials, > 60% of patients with treatment-naïve neovascular age-related macular degeneration (nAMD) achieved every-16-week (Q16W) faricimab dosing and almost 80% achieved ≥ Q12W dosing at week 112. These post hoc analyses of pooled data from TENAYA/LUCERNE evaluated the baseline and early treatment response variables associated with always extended (≥ Q12W) dosing and the predictors of patients who could have extended to Q20W faricimab dosing.
Methods: Patients received faricimab 6.0 mg up to Q16W after 4 Q4W loading doses. Following disease activity assessments at weeks 20/24, patients received fixed dosing up to Q16W until week 60 and then a treat-and-extend-(T&E)–based dosing regimen. Univariate analyses were performed to evaluate the association between baseline and early treatment response variables and always extended dosing (≥ Q12W) from week 20/24 through to week 112. In addition, univariate followed by multivariable analyses evaluated the association between baseline and early treatment response variables and patient eligibility for potential Q20W extension during the T&E dosing phase. *P* values are nominal and not adjusted for multiplicity.
Results: Compared with patients who received at least 1 Q8W cycle from week 20/24 through to week 112 (n = 248), patients always on extended dosing (n = 310) had lower baseline central subfield thickness (345 µm vs 374 µm; $P = 0.0060$), lower baseline pigment epithelial detachment (PED) thickness (215 µm vs 315 µm; $P < 0.0001$) and PEDs at baseline that were more often fibrovascular (85% vs 73%; $P = 0.0008$). Corresponding multivariable analysis results for patients on always extended dosing will be reported. The odds (odds ratio [95% CI]) for potential Q20W extension during the T&E phase (n = 591) increased with baseline presence of IRF (1.5 [1.1–2.1]), lower maximum PED thickness at baseline (1.3 [1.2–1.5]), and the absence of subretinal fluid at week 12 (2.4 [1.4–4.1]).

Conclusion: These TENAYA/LUCERNE post hoc analyses provide further insights into factors associated with the extended durability of the dual angiopoietin-2/vascular endothelial growth factor-A inhibitor, faricimab, in treatment-naïve patients with nAMD, and support that early fluid resolution with faricimab contributes to extended durability and improved outcomes.

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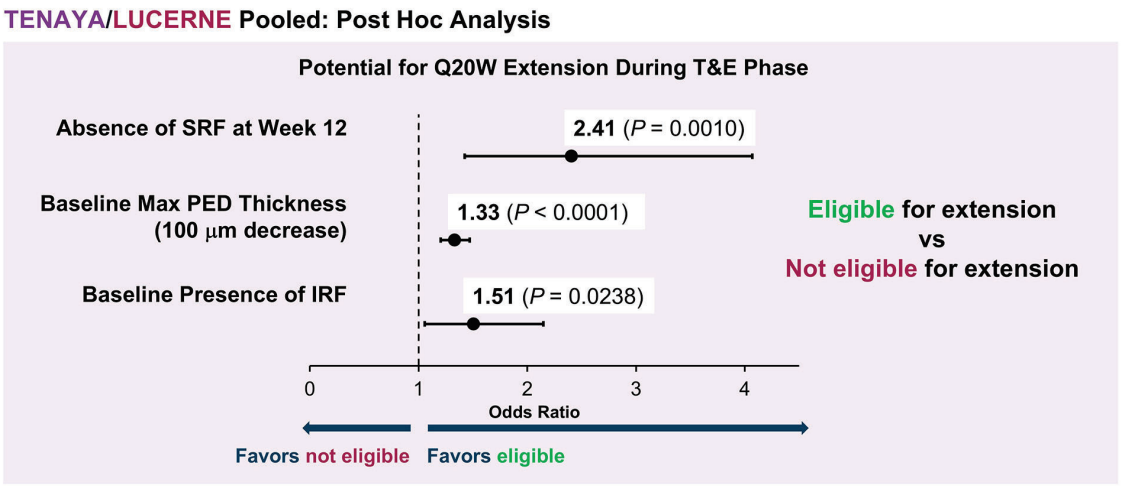

Hypothetical Q20W extension followed the same criteria in BCVA and CST vs their reference values as used in the phase 3 studies. *P*-values are nominal and not adjusted for multiplicity, no formal conclusion should be made based on the *P*-values.
BCVA, best-corrected visual acuity; CST, central subfield thickness; IRF, intraretinal fluid; PED, pigment epithelial detachment; Q20W, every 20 weeks; SRF, subretinal fluid; T&E, treat-and-extend.

Early Drying Was Associated With Eligibility for Potential Q20W Extension

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Wet AMD Symposium 1

Rapid Fluid Resolution With Aflibercept 8 mg May Be Associated With Extended Dosing Intervals at Week 96 in nAMD: A PULSAR Post Hoc Analysis

- Michael Stewart, MD
- Paolo Lanzetta, MD
- Richard Gale
- Javier Zarranz-Ventura, MD, PhD, FEBO
- Sergio Leal
- Tobias Machewitz
- Xin Zhang

Objective: To evaluate whether early fluid resolution (no intraretinal fluid and no subretinal fluid in the central subfield) is associated with extended dosing intervals at Week (W) 96 in patients treated with aflibercept 8 mg in the PULSAR Phase 3 trial.
Purpose: PULSAR (NCT04423718) was a double-masked, 96-week, Phase 3 trial of the efficacy and safety of aflibercept 8 mg in patients with neovascular age-related macular degeneration (nAMD). In this post-hoc analysis of PULSAR, the association between last assigned dosing interval at W96 and early fluid resolution was investigated.
Methods: Patients with nAMD were randomly assigned 1:1:1 to receive aflibercept 2 mg every 8 weeks (2q8) or aflibercept 8 mg every 12 or 16 weeks (8q12 or 8q16) after 3 monthly injections (at W0, W4, and W8). Dosing intervals for patients in the aflibercept 8 mg group could be shortened from W16 to W96 or extended from W52 (to a maximum 24-W interval) based on predefined criteria. Fluid outcomes were assessed at W4, W8, and W12 in patients who completed 96 weeks of treatment. The association between fluid resolution at W4, W8, and W12 and last assigned dosing interval in patients who received aflibercept 8 mg was analyzed (regardless of fluid outcomes at other timepoints).

Results: Overall, 55.9%, 50.8%, and 48.5% of patients receiving aflibercept 8 mg (n=583) and 49.7%, 43.7%, and 39.9% of patients receiving aflibercept 2 mg (n=286) were fluid-free at W4, at W4 and W8, and at W4, W8, and W12, respectively. Of patients in the 8 mg group who had fluid resolution at W4 (n=326), 74.8% and 52.8% had a last dosing interval of ≥Q16 and ≥Q20 at W96, respectively. Of patients in the 8 mg group who had fluid resolution at W4 and W8 (n=296), 76.0% and 53.4% had a last dosing interval of ≥Q16 and ≥Q20 at W96, respectively. Of patients in the 8 mg group who had fluid resolution at W4, W8, and W12 (n=283), 76.3% and 53.7% had a last dosing interval of ≥Q16 and ≥Q20 at W96, respectively. Conversely, the proportion of patients in the 8 mg group who did not have fluid resolution at W4, W8, or W12 was 16.8% (n=98). Fewer of these patients had a last dosing interval of ≥Q16 and ≥Q20 at W96 (64.3% and 36.7%, respectively) compared to those who had some rapid fluid resolution. All subgroups described largely maintained their visual and anatomic improvements from W12 to W96.
Conclusion: Rapid fluid resolution in the initial monthly dosing period may be associated with extended dosing intervals in patients who received aflibercept 8 mg for nAMD.

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PULSAR Extension: Clinical Improvements Sustained Over 156 Weeks With Aflibercept 8 mg in Patients With Neovascular Age-Related Macular Degeneration

- David Wong, MD, FRCS(C), DRCPSC, FASRS
- Timothy Lai
- Tien Wong
- Paolo Lanzetta, MD
- Jean-Francois Korobelnik, MD
- Frank Holz, MD, FEBO
- Taji Sakamoto
- Sobha Sivaprasad, FRCOphth
- Andrea Schulze
- Ursula Schmidt-Ott, MD
- Xin Zhang
- Alyson Berliner, MD, PhD
- Karen Chu, MS
- Sergio Leal

Objective: To describe long-term treatment outcomes with aflibercept 8 mg over 156 weeks in patients with neovascular age-related macular degeneration (nAMD) who participated in an extension of the PULSAR study.
Purpose: The PULSAR Extension aimed to evaluate long-term data on treatment outcomes with aflibercept 8 mg in patients with nAMD over 156 weeks.
Methods: In the 96-week, Phase 3 PULSAR trial (NCT04423718), treatment-naïve patients with nAMD were randomly assigned to receive either aflibercept 8 mg every 12 weeks (8q12) or 16 weeks (8q16), or aflibercept 2 mg every 8 weeks (2q8), each after 3 initial monthly doses. Patients who completed the main phase of PULSAR through Week 96 were eligible for an optional 1-year open-label extension through Week 156. From Week 96, patients originally assigned to the 2q8 arm were switched to aflibercept 8 mg and immediately assigned a 12-week dosing interval (2mg→8mg group), and patients originally assigned to the 8q12 and 8q16 arms continued to receive aflibercept 8 mg at their last assigned dosing interval (8mg group). From Week 100, dosing intervals were modified in both groups if prespecified disease activity criteria were met, with 8 weeks and 24 weeks as the minimum and maximum dosing intervals allowed, respectively. Endpoints at Week 156 included change from baseline in best-corrected visual acuity (BCVA). All endpoints at Week 156 were exploratory and analyzed descriptively.
Results: At Week 156, the 2mg→8mg group (n=208) and 8mg group (n=417) reported a least-squares mean change from baseline in BCVA of +4.6 and +3.4 letters and central subfield retinal thickness (CRT) of –145 and –148 µm, respectively. On average, BCVA and CRT improvements at Week 96 were sustained through Week 156. Among patients who completed Week 156, the last assigned dosing interval was ≥12, ≥16, and 20 weeks in 78%, 42%, and 12% in the 2mg→8mg group, respectively, and ≥12, ≥16, ≥20, and 24 weeks in 77%, 58%, 40%, and 24%, respectively, in the 8mg group. No new safety signals were identified through Week 156.
Conclusion: In the PULSAR Extension, functional and anatomic improvements were sustained through Week 156 in the 2mg→8mg and 8mg groups. These findings suggest that patients with treatment-naïve nAMD experience durable improvements with aflibercept 8 mg administered over extended dosing intervals.

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Indirect Comparison of the Relative Effectiveness of Faricimab vs Aflibercept 8 mg in DME and nAMD

- Nikolas London, MD, FACS, FASRS
- Pearse Keane, MD
- Nancy Holekamp, MD, FASRS
- Theodore Leng, MD, MS, FASRS
- Jakob Siedlecki, PD Dr med
- Florie Mar, PhD
- Kara Gibson, PhD
- Philippe Margaron, PhD
- Christian Buehrer, PhD
- David Tabano, PhD

Objective: To use phase 3 trial data in a match-adjusted network meta-analysis (NMA) to indirectly compare effectiveness of faricimab and aflibercept 8 mg in diabetic macular edema (DME) and neovascular age-related macular degeneration (nAMD).
Purpose: To perform an NMA of the efficacy of faricimab vs aflibercept 8 mg at week 12 (after 3 loading doses) by matching patient populations in phase 3 trials for DME (YOSEMITE/RHINE and PHOTON) and nAMD (TENAYA/LUCERNE and PULSAR).
Methods: Weighting was applied to match patients from YOSEMITE/RHINE (NCT03622580/NCT03622593) and TENAYA/LUCERNE (NCT03823287/NCT03823300) based on their baseline characteristics to published aggregated baseline characteristics for PHOTON (NCT04429503) and PULSAR (NCT04423718), respectively. The matched population was used to recalculate outcomes from faricimab trials and an NMA anchored to the common comparator aflibercept 2 mg was conducted. The analysis focused on change in best-corrected visual acuity (BCVA) in Early Treatment Diabetic Retinopathy Study letters and central subfield thickness (CST) in µm during the first 12 weeks of treatment when dosing was matched. Results are expressed as mean difference in change in BCVA or CST for each aflibercept dose. Limitations include potential variations in characteristics not observed/reported, and that PHOTON/PULSAR data are only available as aggregated means.
Results: For DME, BCVA change from baseline at 12 weeks was similar between faricimab and aflibercept 2 mg (-0.2 letters, 95% credible interval [CrI], -0.9, 0.5) and 8 mg (-0.8 letters, 95% CrI, -2.2, 0.7); CST reduction was greater for faricimab vs aflibercept 2 mg (-19.0 µm, 95% CrI, -27.0, -12.0) and 8 mg (-19.0 µm, 95% CrI, -35.0, -3.2) (Figure). For nAMD, BCVA change was similar between faricimab and aflibercept 2 mg (-0.4 letters, 95% CrI, -1.4, 0.6) and 8 mg (-1.3 letters, 95% CrI, -2.8, 0.3); CST reduction was greater for faricimab vs aflibercept 2 mg (-19.0 µm, 95% CrI, -24.0, -13.0) and 8 mg (-17.0 µm, 95% CrI, -25.0, -8.4) (Figure).
Conclusion: In a match-adjusted NMA, faricimab showed greater CST improvements vs aflibercept 8 mg in DME and nAMD 4 weeks after the third loading dose. Early treatment with a dual pathway inhibitor may improve outcomes beyond anti-vascular endothelial growth factor monotherapy.

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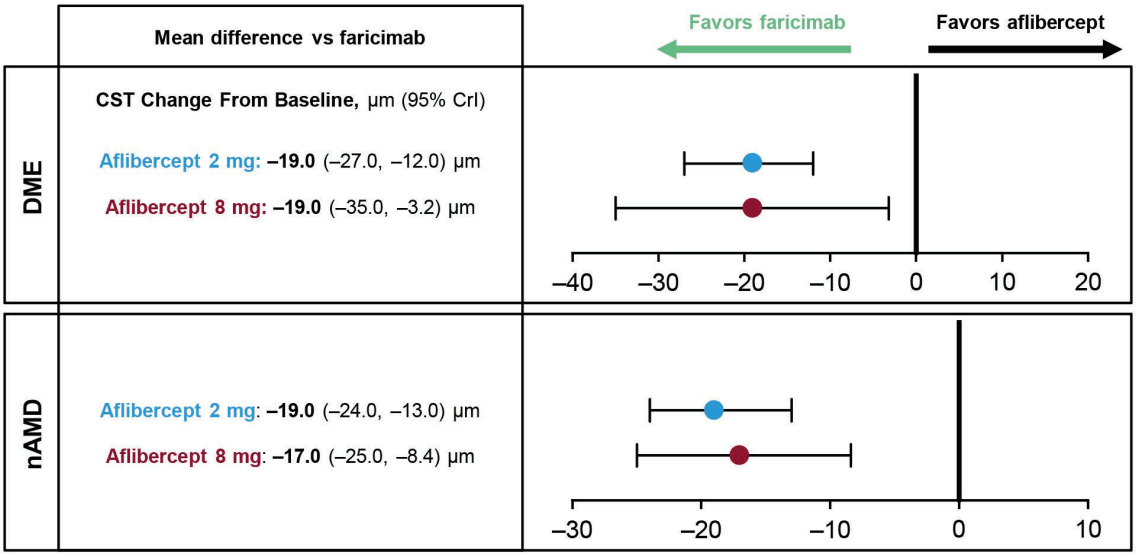

Patient populations matched for mean and SD of the following baseline characteristics: Age, BCVA, CST, proportion of patients with prior anti-VEGF treatment, proportion of patients with DRSS score: absent, mild or moderate, proportion of patients with DRSS score: moderately severe, severe. Weighted outcomes compared using Bayesian network meta-analysis using fixed effects. BCVA, best-corrected visual acuity; CST, central subfield thickness; CrI, credible interval; DME, diabetic macular edema; DRSS, Diabetic Retinopathy Severity Scale; ETDRS, Early Treatment Diabetic Retinopathy Study; NMA, network meta-analysis.

8/01/2025

Wet AMD Symposium 1

5-Year Outcomes in nAMD Patients Enrolled in the Archway Study and Treated With the PDS

- John Kitchens, MD
- Gian Andrea-Thanei, MS
- Steven Blotner, PhD
- Shamika Gune, MD
- Mel Rabena, BS
- Natasha Singh, Pharm D

Objective: To evaluate the 5-year efficacy and safety outcomes of neovascular age-related macular degeneration (nAMD) patients enrolled in the phase 3 Archway (NCT03677934) trial of the PDS who entered the ongoing Portal extension trial (NCT03683251).

Purpose: Long-term outcomes in patients who returned for a single assessment after exiting the 2-year CATT and IVAN trials of anti-vascular endothelial growth factor (VEGF) injections in nAMD showed that vision gains made during the study were lost in the years following trial exit when patients were managed in clinical practice per standard of care, with mean best-corrected visual acuity (BCVA) declining by 11 letters over 3.5 years and 19.7 letters over 5.3 years, respectively. These data provide proof that nAMD patients in the real-world experience suboptimal outcomes. The Port Delivery Platform is a drug delivery system that continuously delivers customized medicines to the eye, with the Port Delivery Platform with ranibizumab (PDS) as the first combination. Here we present 5-year safety and efficacy of PDS refilled every 24 weeks (PDS Q24W) in the Archway-Portal extension trial where nAMD patients were followed prospectively for 240 weeks (5 years).

Methods: Archway was a phase 3, randomized, active treatment–controlled trial comparing PDS Q24W with intravitreal ranibizumab 0.5 mg injections every 4 weeks for the treatment of nAMD. Patients with nAMD who were previously treated with and responsive to anti-VEGF treatment were randomized 3:2 to PDS Q24W (n = 248) or intravitreal (IVT) ranibizumab 0.5 mg injections every 4 weeks (monthly ranibizumab; n = 167). Patients had received a mean of 5 anti-VEGF injections before randomization. Archway evaluated the safety and efficacy of PDS Q24W for 2 years (96 weeks, 4 full treatment intervals). Patients who completed the study at week 96 were eligible to enter the open-label extension study, Portal.
In Portal, patients who were treated with the PDS in Archway continued to receive PDS Q24W upon entering Portal (PDS cohort). Patients who received monthly ranibizumab in Archway were offered the opportunity to undergo PDS implant insertion and initial fill with ranibizumab 100 mg/mL at Portal entry and then received refill-exchanges Q24W (IVT-PDS cohort).

Results: The Archway cohort (PDS cohort, n=220; IVT-PDS cohort, n= 132) of Portal patients included patients with a follow-up time of 240 weeks since enrollment in the Archway trial. In the PDS cohort, mean (95% confidence interval [CI]) BCVA at baseline and at week 240 were 74.4 (73.0, 75.8) and 67.6 (65.2, 70.0) letters, respectively, with a mean (95% CI) BCVA change from baseline at week 240 of -7.2 (-9.4, -5.1) letters and median BCVA at week 240 of 73.0 letters (median change from baseline: -4.0 letters). In the IVT-PDS cohort, mean (95% CI) BCVA at baseline and at week 240 were 76.3 (74.7, 78.0) and 68.6 (65.3, 71.9) letters, respectively with a mean (95% CI) BCVA change from baseline at week 240 of -7.6 (-10.5, -4.6) letters and median BCVA at week 240 of 73.5 letters (median change from baseline: -4.5 letters). The mean (95% CI) central subfield thickness (CST) at baseline was 308.8 (296.3, 321.3) and 300.6 (288.9, 312.2) µm in the PDS and IVT-PDS cohorts, respectively, whereas the CST change from baseline at week 240 was -1.0 (-13.1, 11.1) and -10.3 (-25.7, 5.0) µm. PDS treatment was generally well tolerated with a consistent safety profile over 5 years. The incidence of endophthalmitis was 2.8% in all study eyes implanted with PDS.

Conclusion: Archway-Portal is the largest dataset of anti-VEGF treated nAMD patients to be followed prospectively and continuously for 5 years in the clinical trial setting, establishing the long-term efficacy and safety of PDS. In this population of nAMD patients previously treated with 5 injections who were at or near peak vision at study baseline, continuous delivery of ranibizumab via the PDS provided consistent anatomic control with a mean 7-letter decline over 5 years, likely due to a ceiling effect followed by the expected natural progression of AMD in this aging population. 50% of patients maintained 20/35 Snellen vision over 5 years. The long-term safety profile is well characterized and was generally well tolerated with a consistent profile over these 5 years. These data provide evidence to support the PDS as a compelling treatment choice for nAMD patients in clinical practice. The Portal study is ongoing and is expected to provide even longer-term data in patients with nAMD.

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8/01/2025

Randomized, Controlled, Double-Masked Study to Evaluate the Efficacy of IRX-101 in Reducing Post-Intravitreal Injection Pain and Corneal Toxicity: RELIEF Trial Results

- Karen Wai, MD
- John Kitchens, MD
- David Brown, MD
- Cagri Besirli, MD, PhD, FASRS
- Stephen Smith, MD

Objective: To evaluate the safety and efficacy of IRX-101, a novel ocular antiseptic, in reducing post-intravitreal injection pain and corneal epitheliopathy compared to 5% povidone-iodine.
Purpose: Despite frequently causing corneal toxicity and post-intravitreal injection (IVI) pain and carrying a contra-indication for patients with iodine sensitivity, 5% Povidone-iodine (PI) is nearly universally used as an ocular antiseptic prior to IVI due to the lack of FDA approved alternatives. IRX-101 is a broad spectrum, novel, corneal-sparing ocular antiseptic that consists of purified and stable aqueous chlorine-dioxide which has been shown to have superior antimicrobial efficacy compared to PI in time-kill and peri-ocular microflora studies. The objective of the RELIEF trial was to evaluate the superiority of IRX-101 compared to PI with respect to post-IVI pain and corneal epitheliopathy when used prior to IVI.
Methods: RELIEF was a prospective, multicenter, randomized, double-masked phase 1b/2b clinical study in participants undergoing anti-VEGF IVI. Following establishment of safety in the Phase 1b portion (Cohort 1) with 2-minute exposure time, the 2b portion (Cohort 2) was initiated, which reduced exposure time to 30 seconds for both IRX-101 and PI. Participants were randomized (2:1) to receive IRX-101 or 5% PI. RELIEF Cohort 2 had two primary endpoints: (1) Post-injection corneal fluorescein staining (CFS, scale 0 to 5, modified Oxford grading scheme) score, and (2) Participant-reported pain score (visual analog pain scale, 0 to 10) one hour after treatment and IVI. Exploratory outcomes included patient preference determined via a telephone call (TC) one hour after treatment and IVI. Prespecified subgroup analyses were performed in patients that were identified as sensitive to PI. All subjects received ocular examinations before and after treatment to assess safety, with a TC to assess adverse events 1 hour and 1 week after IVI.
Results: Thirty-three (33) participants were included in Cohort 1. Following two minutes of exposure, IRX-101 was well-tolerated; adverse events were primarily mild with no severe adverse events and no serious adverse events. In Cohort 2, 155 participants were enrolled and treated with either IRX-101 (n=102) or PI (n=52). Mean pain scores were significantly lower with IRX-101 (0.74, standard deviation (SD) 0.85) vs PI (1.49, SD 1.79) (p=0.0003). Mean CFS scores were significantly lower for IRX-101 (2.04, SD 0.94) vs PI (2.63, SD 1.15) (p=0.0003). At 1-hour post TC, participants who received IRX-101 were more likely than those who received PI to report that they were “happier than previous injection” (47% vs 25%, p=0.001), and less likely to report that they were “less happy than previous injection” (2.9% vs 15.4%, p=0.001). In the pre-specified subgroup who were identified as sensitive to PI (n=79; 52 in the IRX-101 group, 27 in the PI group) both mean pain score (1.21, SD 0.60 vs 1.89, SD 1.42 (p=0.0042) and CFS score (1.74, SD 0.68 vs 2.26, SD 0.81) (p=0.0012) were significantly lower after IRX-101 vs PI. In this subgroup analysis, patients who received IRX-101 were more likely than patients who received PI to report that they were “happier than previous injection” (65.4% vs 33.3%, p=0.001), and less likely to report that they were “less happy than previous injection” (5.8% vs 14.8%, p=0.001). Safety data for IRX-101 relative to PI showed a favorable safety profile, with fewer total adverse events deemed related to study drug (45.6% vs 67.3%) and no cases of infectious endophthalmitis in either group.
Conclusion: In the RELIEF trial, IRX-101 was well tolerated with both 2-minute exposure and 30 second exposure in the phase 1b portion. In the Phase 2b portion, IRX-101 use significantly improved antiseptic-induced corneal toxicity as demonstrated by lower pain score and CFS score in patients undergoing IVI compared to 5% PI. In addition to the superior antimicrobial efficacy of IRX-101 compared to PI shown in time-kill and peri-ocular antimicrobial efficacy studies, the RELIEF trial results support continued clinical development of IRX-101 as a novel ocular antiseptic agent with better tolerability compared to PI, which is expected to provide an improved IVI experience for patients, including those with iodine sensitivity.

IRB APPROVAL Yes

8/01/2025

Efficacy and Safety of Biosimilar Aflibercept-ayyh in Clinical Use by a Consortium of Retina Practices

- Carl Awh, MD, FASRS
- James Lin, MD, FASRS

Objective: Are there unexpected outcomes from treatment with biosimilar aflibercept-ayyh?

Purpose: New pharmacologic therapies may have effects that were not observed or anticipated in clinical research trials but that become apparent in clinical use. This analysis of eyes treated by multiple retina specialists in different practices across the United States can provide useful information about the treatment response to the biosimilar agent aflibercept-ayyh. These outcomes may be of interest to retina specialists and patients as they consider treatment with these new biosimilar agents.

Methods: This is a retrospective, non-randomized, consecutive case series of eyes receiving aflibercept-ayygh at a large consortium of retina practices across the US. Electronic medical records (EMR) were reviewed for each patient with follow-up of at least 28 days following the first injection (defined as the baseline injection) with aflibercept-ayyh. Clinical information was recorded; including baseline demographics, diagnosis, the number of prior anti-VEGF injections, visual acuity (VA), and the biosimilar agent used. At subsequent visits, VA, the presence of cells in the anterior chamber (AC) or vitreous, diagnosis of uveitis or vasculitis, or other adverse events were recorded. IRB approval was obtained.

Results: Among 21 retina-only group practices 7773 eyes [OD=3980 (51.2%); OS=3793 (48.8%)] of 6313 patients (Female=59.4%; Male=37.4%; Mean Age=79.67 ± 9.0 years) were identified that received aflibercept-ayyhas of March 31, 2025. 6713 eyes had been previously treated with anti-VEGF (mean of 5.85(±2.73, range: 1-23) prior injections per eye). Mean baseline VA was 0.53 LogMar (20/66). Mean VA of eyes examined at approximately 1 (n = 1955), 2 (n = 1393), and 3 (n = 337) months post-baseline was 0.50 (±0.53), 0.54 (±0.56), and 0.57 (±0.62) LogMar. There was no statistically significant difference in overall vision change at any time point post-aflibercept-ayyh injection. 11,036 injections of aflibercept-ayyh were administered. Two eyes (0.01%) with acute endophthalmitis were identified. Seven eyes (0.09%) developed non-serious AC or vitreous cells that did not lead to alteration of treatment with biosimilar aflibercept-ayyh. There were no cases of vasculitis, choroidal detachment, retinal detachment, or newly-diagnosed glaucoma.

Conclusion: To date, 2 cases of endophthalmitis of indefinite etiology but consistent with infectious endophthalmitis and 7 cases of minimal inflammation have been identified following 11,036 injections of biosimilar aflibercept-ayyh. Overall visual acuity remained stable. There was no evidence of serious drug-related inflammation, nor any other unexpected outcomes. These findings suggest that treatment outcomes with aflibercept-ayyh are similar to those of reference product aflibercept.

Note: This data set will be substantially updated with outcomes of additional injections prior to the 2025 ASRS Annual Meeting.

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