LUGANO Phase 3 Trial of Bioerodible EYP-1901 (vorolanib intravitreal insert) vs Aflibercept in Patients with Neovascular Age-Related Macular Degeneration: First-time Safety and Treatment Burden Outcomes

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Disclosures & Disclaimer

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EYP-1901 is an investigational product and its safety and efficacy has not been established. FDA has not approved EYP-1901 in the United States. The materials discussed in this presentation do not predict future FDA approval. Efficacy and safety of EYP-1901 is currently being evaluated in Phase 3 clinical trials.

LUGANO and LUCIA: Phase 3 Pivotal Trials Evaluating Noninferiority of EYP-1901 vs On-Label Aflibercept 2 mg in Wet AMD

Objective

Demonstrate that **EYP-1901**, when administered every 6 months, achieves similar visual outcomes to **on-label aflibercept 2 mg** while reducing treatment burden in patients with wet AMD

Primary endpoint

Difference in mean change in BCVA from Day 1 to Weeks 52 and 56 (averaged) vs aflibercept control (NI margin: −4.5 letters)

Secondary endpoints

- **Anatomy**: CST change from baseline up to Week 96
- **Supplemental treatment:** Proportion of patients not receiving a supplemental injection of aflibercept up to Week 96
- **Treatment burden:** Annualized rate of injection burden through Week 56
- **Safety:** Incidence and severity of ocular TEAE up to Week 96

Inclusion criteria

- **Previously-treated** *or* **treatment-naïve** patients with a documented diagnosis of wet AMD in the study eye, with disease onset at any time before Screening
- **BCVA between 35 to 78 ETDRS letter score** (≈20/32 to 20/200 Snellen equivalent) in the study eye at Screening and Day 1
- Previously-treated patients must have been treated with **≥2 anti-VEGF IVT injections**[a] in the 6 months prior to Screening

Exclusion criteria

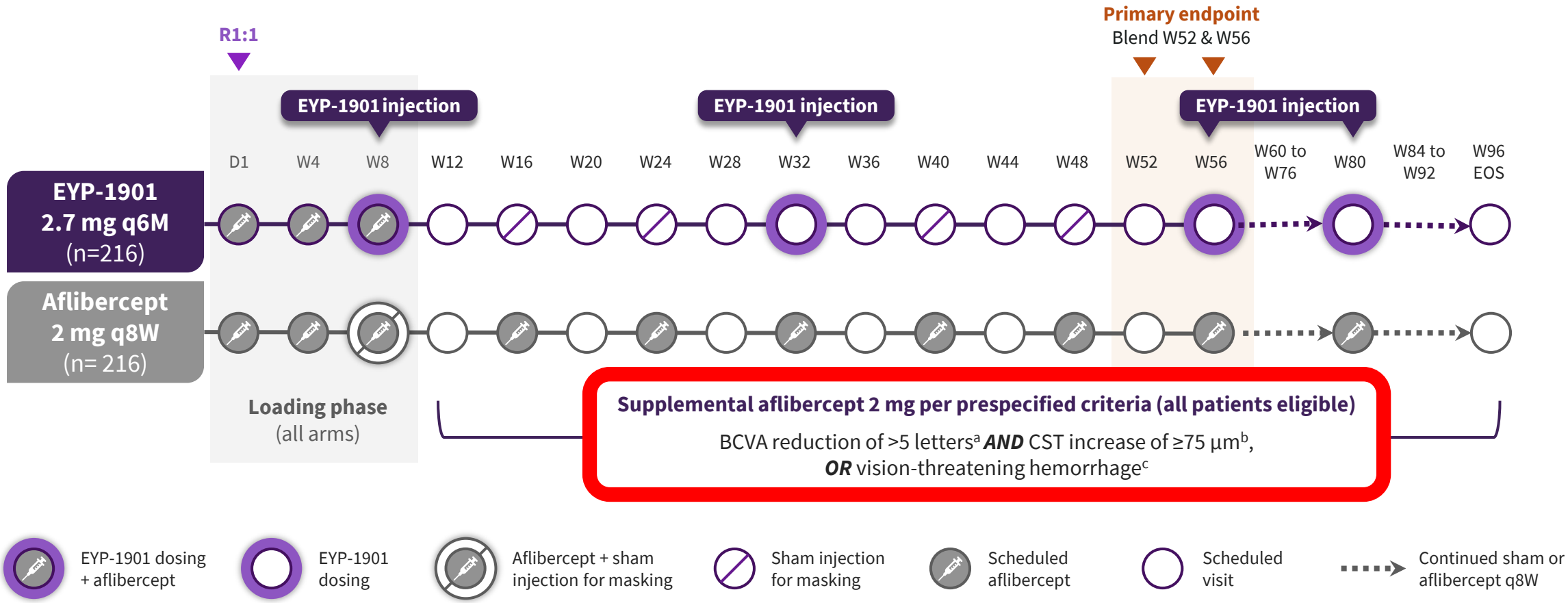
- Subfoveal fibrosis, atrophy, or scarring in the center subfield
- Fellow eye BCVA using ETDRS charts <20 letters (20/400 Snellen equivalent)
- CST >500 µm, RPED >400 µm, retinal pigment epithelial tear
- Uncontrolled ocular hypertension or glaucoma (IOP >25 mmHg or cup to disc ratio ≥0.8
- Presence of signs indicative of polypoidal choroidal vasculopathy as assessed by the Central Reading Center

The EYP-1901 dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. [a]Aflibercept 2 mg, aflibercept 8 mg, bevacizumab (off-label), ranibizumab, or faricimab for wet AMD per standard-of-care in the study eye.
AMD, age-related macular degeneration; **BCVA**, best-corrected visual acuity; **CST**, central subfield thickness; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **NI**, noninferiority; **IOP**, intraocular pressure; **IVT**, intravitreal; **RPED**, retinal pigment epithelial detachment; **TEAE**, treatment-emergent adverse event; **VEGF**, vascular endothelial growth factor. ClinicalTrials.gov identifiers: LUGANO NCT06668064; LUCIA NCT06683742.

Preliminary data – pending final analysis. Efficacy and safety of EYP-1901 is currently being evaluated in Phase 3 clinical trials.

LUGANO: Phase 3 Pivotal Trial Evaluating Noninferiority of EYP-1901 vs On-Label Aflibercept 2 mg in Wet AMD

Patients with treatment-naïve or previously-treated wet AMD



The EYP-1901 dose investigated in phase 3 trials is 2.686 mg (two inserts of 1.343 mg each) administered in a single injection. [a] From best on study measurement due to wet AMD. [b] From lowest on study measurement. Increase in CST must be due to subretinal and/or intraretinal fluid. [c] Requires discussion with supplemental injection monitor.

AMD, age-related macular degeneration; **BCVA**, best-corrected visual acuity; **CST**, central subfield thickness; **D**, day; **EOS**, end of study; **q6M**, every 6 months; **q8W**, every 8 weeks; **R**, randomization; **W**, week.

LUGANO ClinicalTrials.gov identifier: NCT06668064.

Preliminary data – pending final analysis. Efficacy and safety of EYP-1901 is currently being evaluated in Phase 3 clinical trials.

Baseline Characteristics: Well-Balanced Across Treatment Arms

Baseline Characteristics	EYP-1901 2.7 mg q6M (n = 211)	Aflibercept 2 mg q8W (n = 216)
Age (years), mean (SD)	77.5 (7.52)	77.0 (7.61)
Female, n (%)	136 (64.5)	141 (65.3)
History of anti-VEGF treatment, n (%)		
Treatment naïve, n (%)	159 (75.4)	164 (75.9)
Previously treated, n (%)	52 (24.6)	52 (24.1)
Annualized number of anti-VEGF injections, PT patients, mean (SD)	7.35 (2.21)	7.39 (2.01)
Mean time since diagnosis of wet AMD, PT patients, years	3.32	2.66
BCVA (ETDRS letters), mean (SD)	65.8 (8.95)	64.3 (10.35)
> 65 letters, n (%)	115 (54.5)	116 (53.7)
≤ 65 letters, n (%)	96 (45.5)	100 (46.3)
BCVA categories		
> 69 ETDRS letters (20/40 Snellen equivalent), n (%)	82 (38.9)	79 (36.6)
≤ 69 ETDRS letters (20/40 Snellen equivalent), n (%)	129 (61.1)	137 (63.4)
CST (µm), mean (SD)	319.83 (71.43)	326.01 (71.91)
Total CNV area by FA (mm^2), mean (SD)	5.69 (4.44)	4.60 (3.86)

LUGANO enrolled
~75% treatment naïve
~25% previously treated

~7 annualized anti-VEGF injections in previously treated patients

(mean 7.37 injections; range 1-12 injections)

Patients were stratified by baseline BCVA ETDRS score (>65 letters vs ≤65 letters) and history of anti-VEGF therapy for wet AMD (treatment naïve or previously treated). **AMD**, age-related macular degeneration; **BCVA**, best corrected visual acuity; **CNV**, choroidal neovascularization; **CST**, central subfield thickness; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **FA**, fluorescein angiography; **PT**, previously-treated; **q6M**, every 6 months; **q8W**, every 8 weeks; **VEGF**, vascular endothelial growth factor.
LUGANO Clinicaltrials.gov Identifier: NCT06668064.

Preliminary data – pending final analysis. Efficacy and safety of EYP-1901 is currently being evaluated in Phase 3 clinical trials.

Supplemental Injections

54% of patients demonstrated disease control up to Week 56 with EYP-1901 alone

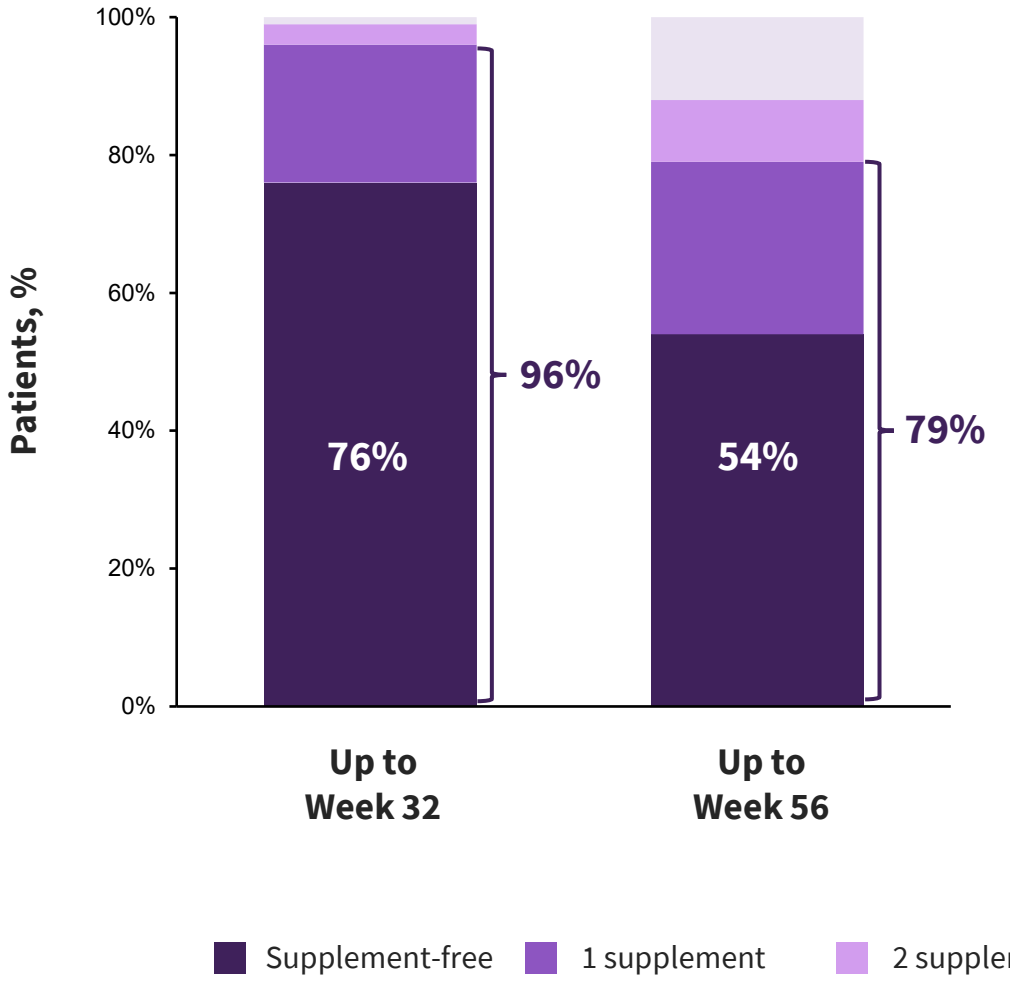
Supplemental treatment:

Patients assessed at each visit starting at Week 12

BCVA reduction of >5 letters[a] ***AND*** CST increase of ≥75 µm[b], ***OR*** vision-threatening hemorrhage[c]

Supplemental Injections Received, Full Analysis Set

(EYP-1901 2.7 mg arm, n=211)



In the EYP-1901 2.7 mg q6M arm:

76% were supplement-free up to Week 32

54% were supplement-free up to Week 56

79% received 0 or 1 supplement up to Week 56

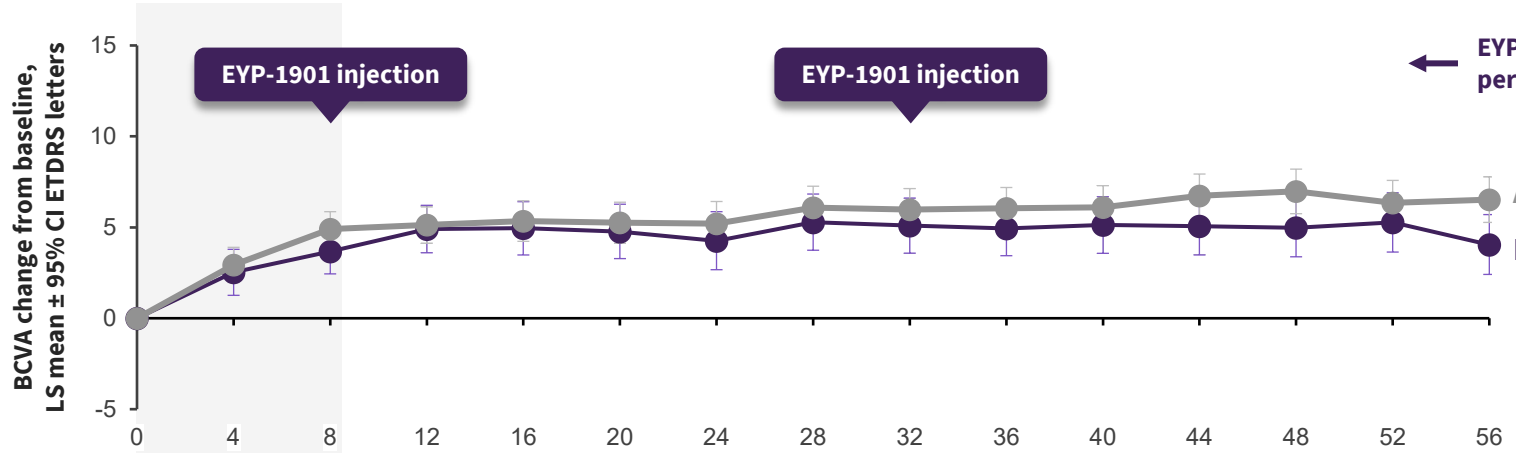
[a] From best on study measurement due to wet AMD. [b] From lowest on study measurement. Increase in CST must be due to subretinal and/or intraretinal fluid. [c] Requires discussion with supplemental injection monitor.

BCVA, best-corrected visual acuity; **CST**, central subfield thickness; **q6M**, every 6 months. LUGANO Clinicaltrials.gov Identifier: NCT06668064.

Preliminary data – pending final analysis. Efficacy and safety of EYP-1901 is currently being evaluated in Phase 3 clinical trials

Supplement-Free Subgroups: Similar Outcomes with EYP-1901 q6M and Aflibercept q8W (EYP-1901 n=113, 54%; Aflibercept n=192, 89%)

Mean BCVA Change from Baseline, Supplement-Free Subgroups



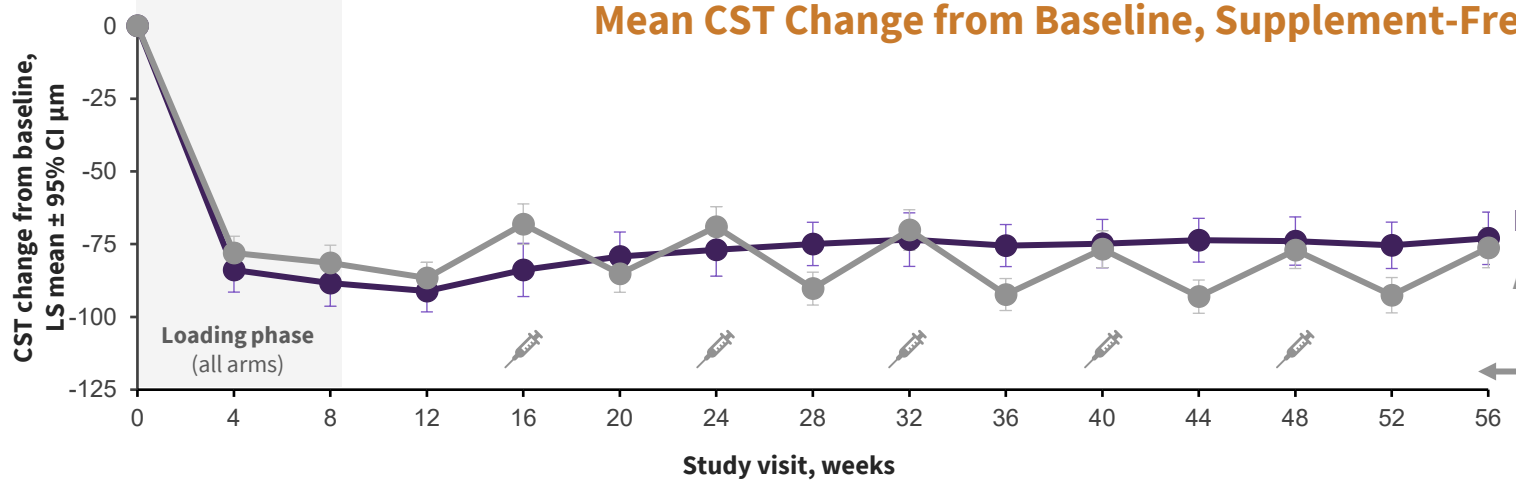
EYP-1901 2.7 mg injections per q6M schedule

BCVA change from baseline, letters	Week 52/56
Aflibercept 2 mg q8W	+6.4
EYP-1901 2.7 mg q6M	+4.7

Difference vs aflibercept q8W **−1.8 letters**

Nominal p=0.0035
95% CI: −3.75, 0.21

Mean CST Change from Baseline, Supplement-Free Subgroups



CST change from baseline, µm	Week 56
EYP-1901 2.7 mg q6M	−73
Aflibercept 2 mg q8W	−76

Aflibercept 2 mg injections per q8W schedule

Difference vs aflibercept q8W **+3 µm**

EYP-1901 2.7 mg q6M, supplement-free, n=113/211 (54%)

Aflibercept 2 mg q8W, supplement-free, n=192/216 (89%)

BCVA, best-corrected visual acuity; **CST**, central subfield thickness; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **LS**, least squares; **q6M**, every 6 months **q8W**, every 8 weeks.
LUGANO Clinicaltrials.gov Identifier: NCT06668064.

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Treatment Burden

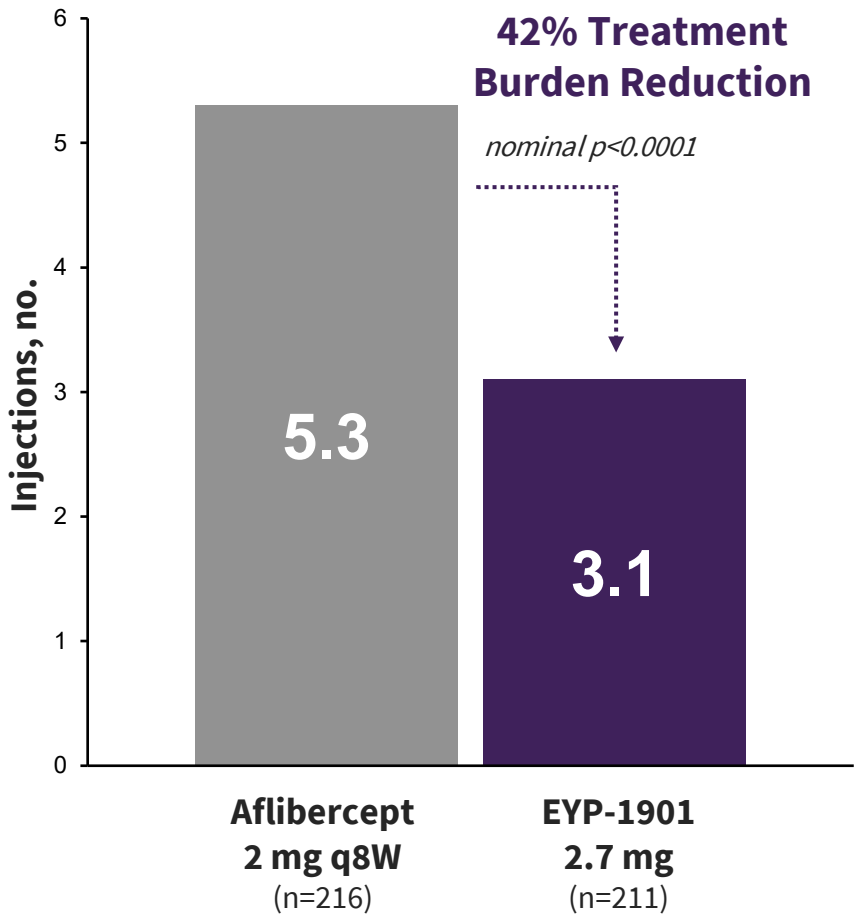
EYP-1901 achieved superiority in injection burden up to Week 56

Treatment burden calculated after loading phase & included supplemental injections and protocol-mandated doses:

5 injections of aflibercept 2 mg:
Weeks 16, 24, 32, 40, 48

2 injections of EYP-1901 2.7 mg:
Weeks 8 and 32

Annualized Injection Burdens Up To Week 56[a], Full Analysis Set



With EYP-1901 at Week 56:

42% reduction in treatment burden versus on-label aflibercept q8W

(Maximum reduction is 60%)

Average of **1.1 supplemental injections** received[b]

2 fewer injections on average versus on-label aflibercept q8W

With aflibercept 2.0 mg at Week 56:

Average of **0.3 supplemental injections** received[b]

[a] Participants who discontinued treatment or study early without any Week 8 or later injections of study drug were not included. For EYP-1901 arm: Number of injections includes EYP-1901 injections at Week 8 and Week 32, and all supplemental injections after Week 8 through Week 56. For aflibercept arm: Number of injections includes all aflibercept and supplemental injections after Week 8 through Week 56. Scheduled aflibercept injections from Day 1 through Week 8 were excluded. Week 56 study treatment injection was excluded from this analysis. [b] Average supplemental injection annualized. **q8W**, every 8 weeks.
LUGANO Clinicaltrials.gov Identifier: NCT06668064.

Preliminary data – pending final analysis. Efficacy and safety of EYP-1901 is currently being evaluated in Phase 3 clinical trials

EYP-1901 Demonstrated a Favorable Ocular Safety Profile with Every 6 Month Redosing

n (%)	EYP-1901 2.7 mg q6M (n=211)	Aflibercept 2 mg q8W (n=221[a])
Non-ocular TEAEs		
Any TEAE	142 (67.3)	151 (68.3)
Any serious TEAE	34 (16.1)	30 (13.6)
Any TEAE leading to study treatment discontinuation	2 (0.9)	1 (0.5)
Any TEAE leading to study discontinuation	1 (0.5)	1 (0.5)
Any TEAE leading to death	1 (0.5)	3 (1.4)
Ocular TEAEs in the Study Eye		
Any TEAE	119 (56.4)	111 (50.2)
Any serious TEAE	3 (1.4)	1 (0.5)
Any TEAE leading to study treatment discontinuation	0	1 (0.5)
Any TEAE leading to study discontinuation	0	1 (0.5)

Safety Analysis Set. [a] Five patients that were randomized into the EYP-1901 arm but discontinued before EYP-1901 administration were included in the aflibercept 2 mg arm for safety analyses. **q6M**, every 6 months; **q8W**, every 8 weeks, **TEAE**, treatment-emergent adverse event. LUGANO Clinicaltrials.gov Identifier: NCT06668064.

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EYP-1901 Demonstrated a Favorable Ocular Safety Profile with Every 6 Month Redosing

Ocular AEs in Study Eye ≥ 2% Through Week 56, n (%)	EYP-1901 2.7 mg q6M (n=211)	Aflibercept 2 mg q8W (n=221[a])
Conjunctival hemorrhage	24 (11.4)	11 (5.0)
Vitreous floaters	19 (9.0)	8 (3.6)
Neovascular age-related macular degeneration	15 (7.1)	3 (1.4)
Retinal hemorrhage	10 (4.7)	4 (1.8)
Vitreous detachment	10 (4.7)	9 (4.1)
Cataract	9 (4.3)	12 (5.4)
Dry eye	9 (4.3)	14 (6.3)
Posterior capsule opacification	9 (4.3)	5 (2.3)
Intraocular pressure increased	8 (3.8)	7 (3.2)
Visual acuity reduced	8 (3.8)	12 (5.4)
Retinal edema	6 (2.8)	2 (0.9)
Visual impairment	5 (2.4)	0
Dry age-related macular degeneration	5 (2.4)	7 (3.2)
Eye pain	5 (2.4)	2 (0.9)
Subretinal fluid	5 (2.4)	3 (1.4)

In the EYP-1901 arm, there were no cases of:

- Insert migration into the anterior chamber
- Anterior chamber opacities
- Free-floating particles
- Retinal vasculitis (occlusive or non-occlusive)
- Severe intraocular inflammation

Safety Analysis Set. [a] Five patients that were randomized into the EYP-1901 arm but discontinued before EYP-1901 administration were included in the aflibercept 2 mg arm for safety analyses. **AE**, adverse event; **q6M**, every 6 months; **q8W**, every 8 weeks; **TEAE**, treatment-emergent adverse event. LUGANO Clinicaltrials.gov Identifier: NCT06668064.

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EYP-1901 Demonstrated a Favorable Ocular Safety Profile with Every 6 Month Redosing

Serious Treatment-Emergent AEs, Safety Analysis Set

Serious TEAEs in Study Eye Through Week 56, n (%)	EYP-1901 2.7 mg q6M (n=211)	Aflibercept 2 mg q8W (n=221[a])
Endophthalmitis	2 (0.9)	0
Retinal detachment	1 (0.5)	1 (0.5)

Intraocular Inflammation, Safety Analysis Set

Intraocular Inflammation in Study Eye Through Week 56, n (%)	EYP-1901 2.7 mg q6M (n=211)	Aflibercept 2 mg q8W (n=221[a])
Uveitis	1 (0.5)	0
Iritis	0	1 (0.5)
Vitritis	0	1 (0.5)

[a] Five patients that were randomized into the EYP-1901 arm but discontinued before EYP-1901 administration were included in the aflibercept 2 mg arm for safety analyses.
AE, adverse event; **q6M**, every 6 months; **q8W**, every 8 weeks; **TEAE**, treatment-emergent adverse event.
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Uveitis	1 (0.5)	0
Iritis	0	1 (0.5)
Vitritis	0	1 (0.5)

Case 1
- Culture: negative
- Onset at Week 32 s/p EYP-1901
- Treated with IVT antibiotics
- **BL BCVA: 65; Week 56 BCVA: 64**

Case 2
- Culture: *S. epidermidis*
- Onset at Week 8 s/p combination aflibercept and EYP-1901
- Treated with IVT antibiotics and vitrectomy
- **BL BCVA: 69; Week 56 BCVA: 66**

[a] Five patients that were randomized into the EYP-1901 arm but discontinued before EYP-1901 administration were included in the aflibercept 2 mg arm for safety analyses.
AE, adverse event; **BCVA**, best-corrected visual acuity; **BL**, baseline; **IVT**, intravitreal; **q6M**, every 6 months; **q8W**, every 8 weeks; **s/p**, status post; **TEAE**, treatment-emergent adverse event.
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Endophthalmitis	2 (0.9)	0
Retinal detachment	1 (0.5)	1 (0.5)

Both Successfully Repaired with PPV

EYP-1901
- Phakic
- 40-letter VA loss at W56 associated with cataract & epiretinal membrane

Aflibercept
- Pseudophakic
- 1-letter VA gain at W56

Intraocular Inflammation, Safety Analysis Set

Intraocular Inflammation in Study Eye Through Week 56, n (%)	EYP-1901 2.7 mg q6M (n=211)	Aflibercept 2 mg q8W (n=221[a])
Uveitis	1 (0.5)	0
Iritis	0	1 (0.5)
Vitritis	0	1 (0.5)

[a] Five patients that were randomized into the EYP-1901 arm but discontinued before EYP-1901 administration were included in the aflibercept 2 mg arm for safety analyses.
AE, adverse event; **q6M**, every 6 months; **PPV**, pars plana vitrectomy; **q8W**, every 8 weeks; **TEAE**, treatment-emergent adverse event; **VA**, visual acuity; **W**, week.
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Intraocular Inflammation, Safety Analysis Set

Intraocular Inflammation in Study Eye Through Week 56, n (%)	EYP-1901 2.7 mg q6M (n=211)	Aflibercept 2 mg q8W (n=221[a])
Uveitis	1 (0.5)	0
Iritis	0	1 (0.5)
Vitritis	0	1 (0.5)

2 patients with IOI overall:
1 in each arm
Both continued per-protocol treatment

EYP-1901: 1 patient

- **Anterior uveitis:** Week 8, moderate
- Treated with topical steroid
- Resolved in 14 days
- No recurrence after 2nd EYP-1901 dose
- No change in vision; no retinal involvement or vasculitis

[a] Five patients that were randomized into the EYP-1901 arm but discontinued before EYP-1901 administration were included in the aflibercept 2 mg arm for safety analyses.
AE, adverse event; **IOI**, intraocular inflammation; **q6M**, every 6 months; **q8W**, every 8 weeks; **TEAE**, treatment-emergent adverse event.
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Endophthalmitis	2 (0.9)	0
Retinal detachment	1 (0.5)	1 (0.5)

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Uveitis	1 (0.5)	0
Iritis	0	1 (0.5)
Vitritis	0	1 (0.5)

2 patients with IOI overall:
1 in each arm
Both continued per-protocol treatment

Aflibercept: 1 patient

- **Iritis:** Week 21, mild
- **Vitritis:** Week 52, moderate
- Treated with topical steroid
- No change in vision; no retinal involvement or vasculitis

[a] Five patients that were randomized into the EYP-1901 arm but discontinued before EYP-1901 administration were included in the aflibercept 2 mg arm for safety analyses.
AE, adverse event; **IOI**, intraocular inflammation; **q6M**, every 6 months; **q8W**, every 8 weeks; **TEAE**, treatment-emergent adverse event.
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LUGANO Phase 3 Trial of EYP-1901 2.7 mg q6M vs Aflibercept 2 mg q8W in Wet AMD

- **54% of patients supplement-free** at one year with stable vision and CST with EYP-1901
- **42% reduction in treatment burden** with EYP-1901 compared with aflibercept 2 mg every 8 weeks
- **Favorable safety profile** with EYP-1901 redosed every 6 months with no events of free-floating particles or retinal vasculitis

LUCIA TOPLINE RESULTS EXPECTED Q4 2026

Second pivotal wet AMD trial

AMD, age-related macular degeneration; **CST**, central subfield thickness; **q6M**, every 6 months; **q8W**, every 8 weeks. Clinicaltrials.gov identifiers: LUGANO, NCT06668064; LUCIA, NCT06683742.

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- Nauman Chaudhry, Retina Group of New England, PC, Waterford, CT
- David Chin Yee, Georgia Retina, Marietta, GA
- Ross Chod, RSC Research, PLLC, Denver, CO
- Lori Coors, Texas Retina Associates, Plano, TX
- Gordon Crabtree, University of Wisconsin-Madison, Department of Ophthalmology & Visual Sciences, Madison, WI
- Ashley Crane, Retina Vitreous Associates of Florida, Tampa, FL
- Matthew Cunningham, Florida Retina Institute, Orlando, FL
- Andrew Davis, Salt Lake Retina, West Jordan, UT
- Amr Dessouki, Retinal Diagnostic Center, Campbell, CA
- Dilsher Dhoot, California Retina Consultants, Bakersfield, CA
- Evan Dunn, Retina Specialists of Tampa, Wesley Chapel, FL
- Gawain Dyer, San Antonio Eye Center, San Antonio, TX
- Albert Edwards, Verum Research, LLC, Eugene, OR
- Naomi Falk, Retina Consultants, PLLC, Slingerlands, NY
- Kenneth Fan, Retina Consultants of Texas, The Woodlands, TX
- Neil Finnen, Midwest Eye Institute, Carmel, IN
- Scott Friedman, Florida Retina Consultants, Lakeland, FL
- Mitchell Goff, Rocky Mountain Retina Consultants, Salt Lake City, UT
- Roger Goldberg, Bay Area Retina Associates, Walnut Creek, CA
- Shilpa Gulati, Retina Research Institute at New England Retina Consultants, Springfield, MA
- Sunil Gupta, Retina Specialty Institute, Pensacola, FL
- Shailesh Gupta, Advanced Research, LLC, Deerfield Beach, FL
- Edward Hall, Retina Associates of Western NY, PC, Rochester, NY
- Jason Handza, Eye Associates of Pinellas, Pinellas Park, FL
- Lindsey Harris, HEA Clinic, PA, Houston, TX
- Allen Hu, Cumberland Valley Retina Consultants, Hagerstown, MD
- Stephen Huddleston, Charles Retina Institute, Germantown, TN
- Golnaz Javey, Piedmont Eye Center, Lynchburg, VA
- Michael Johnson, Charleston Neurosciences Institute, LLC, Charleston, SC
- J. Michael Jumper, West Coast Retina Medical Group, San Francisco, CA
- Christine Kay, Vitreo Retinal Associates, Gainesville, FL
- Arshad Khanani, Sierra Eye Associates, Reno, NV
- Gregg Kokame, Retina Consultants of Hawaii, Aiea, HI
- Baruch Kupperman, Gavin Herbert Eye Institute, Irvine, CA
- Robert Kwun, Retina Associates of Utah, Murray, UT
- Michael Lai, Retina Group of Washington, Chevy Chase, MD
- Gary Lane, Retina Consultants of Texas, San Antonio, TX
- Tamara Lenis, NJRetina, Teaneck, NJ
- Ross Lynds, Strategic Clinical Research Group, LLC, Willow Park, TX
- Andrew McFarland, Retina Associates, PC, Winchester, VA
- Alexander Melamud, The Retina Group of Washington, Fairfax, VA
- Jeffrey Moore, Maine Eye Center, Portland, ME
- Carl Noble, Advanced Vision Surgery Center, Longmont, CO
- Neal Palejwala, Retinal Research Institute at Retinal Consultants of Arizona, Phoenix, AZ
- Justin Parschauer, Tulsa Retina Consultants, Tulsa, OK
- Sunil Patel, Retina Research Institute of Texas Integrated Clinical Research, Abilene, TX
- Hershel Patel, Center for Retina & Macular Disease, Winter Haven, FL
- Sugat Patel, Midwest Retina, Inc., Dublin, Ohio
- John Payne, Palmetto Retina Center, West Columbia, SC
- Randall Peairs, Eye Care Specialists, Kingston, PA
- John Pitcher, Vision Research Center at Eye Associates of New Mexico, Albuquerque, NM
- Jawad Qureshi, Retina Center of Texas, Southlake, TX
- Prethy Rao, Retina & Vitreous of Texas, Bellaire, TX
- Charles Richards, Piedmont Retina Specialists, PA, Winston Salem, NC
- Esther Richter, Retina Group of Florida, Sarasota, FL
- Daniel Roth, NJRetina, Toms River, NJ
- Richard Scartozzi, Connecticut Eye Consultants, PC, Danbury, CT
- Zachary Segal, MedEye Associates, Miami, FL
- Chirag Shah, Ophthalmic Consultants of Boston, Boston, MA
- Omar Shakir, Coastal Eye Surgeons, LLC, Greenwich, CT
- Veeral Sheth, University Retina and Macula Associates, Lemont, IL
- Raymond Sjaarda, Retina Specialists, Towson, MD
- Kent Small, Macula and Retina Institute, Glendale, CA
- Bradley Smith, The Retina Institute, St Louis, MO
- Raafay Sophie, Retina Associates of Michigan, Grand Blanc, MI
- Brittney Statler, Eye Center of Northern Colorado, Fort Collins, CO
- Eric Suan, The Retina Care Center, Baltimore, MD
- Aaron Weinberg, Retina Associates, Elmhurst, IL
- Christina Weng, Baylor College of Medicine Alkek Eye Center, Houston, TX