INTRODUCING CIMERLI® (ranibizumab-eqrn)

The first and only FDA-approved biosimilar interchangeable with Lucentis® (ranibizumab injection) for all indications[1]

INDICATIONS

CIMERLI® (ranibizumab-eqrn) is interchangeable* to Lucentis® (ranibizumab injection)

CIMERLI® (ranibizumab-eqrn), a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)
- Myopic Choroidal Neovascularization (mCNV)

Please see the Important Safety Information throughout this slide deck and the CIMERLI® Prescribing Information.

***An interchangeable product (IP) is a biological product that is approved based on data demonstrating that it is highly similar to an FDA-approved reference product (RP) and that there are no clinically meaningful differences between the products; it can be expected to produce the same clinical result as the RP in any given patient; and if administered more than once to a patient, the risk in terms of safety or diminished efficacy from alternating or switching between use of the RP and IP is not greater than that from the RP without such alternation or switch. Interchangeability of CIMERLI® has been demonstrated for the condition(s) of use, strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information**

1. CIMERLI® (ranibizumab-eqrn) prescribing information. Redwood City, CA: Coherus BioSciences, Inc.

CIMERLI® (ranibizumab-eqrn) injection

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- CIMERLI® is contraindicated in patients with ocular or periocular infections or known hypersensitivity to ranibizumab products or any of the excipients in CIMERLI®. Hypersensitivity reactions may manifest as severe intraocular inflammation

WARNINGS AND PRECAUTIONS

- **Endophthalmitis and Retinal Detachments**: Intravitreal injections, including those with CIMERLI®, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique should always be utilized when administering CIMERLI®. Patients should be monitored following the injection to permit early treatment, should an infection occur
- **Increases in Intraocular Pressure:** Increases in intraocular pressure (IOP) have been noted both pre-injection and post-injection (at 60 minutes) with ranibizumab products. Monitor intraocular pressure prior to and following intravitreal injection with CIMERLI® and manage appropriately
- **Thromboembolic Events:** Although there was a low rate of arterial thromboembolic events (ATEs) observed in the ranibizumab clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause)

CIMERLI® Has Attributes Identical To Lucentis®[1,2*]

Same

FDA-approved indications

Same

Dosage strengths (0.3 mg & 0.5 mg)

Same

Formulation & excipients

Same

Amino acid sequence

*Attributes listed are not exhaustive.

1. CIMERLI® (ranibizumab-eqrn) prescribing information. Redwood City, CA: Coherus BioSciences, Inc. **2.** Data on file. Coherus BioSciences, Inc.

CIMERLI® (ranibizumab-eqrn) injection

CIMERLI® Manufacturing Process Ensures Consistent Product Quality

CIMERLI® is manufactured in state-of-the-art facilities

The facility

Manufacturing facility was purposefully designed to produce therapeutic proteins compliant with all current Good Manufacturing Practices (cGMP) standards, and has successfully completed FDA inspections.

The process

Manufacturing of CIMERLI® has demonstrated a high level of consistency.

The product

CIMERLI® approval was based on extensive data analysis and stringent FDA requirements.

CIMERLI® Demonstrated Biosimilarity Based On The Totality of Evidence

Comparative analytical assessments[1]

Demonstrated similarity of the structural and functional quality attributes of CIMERLI® to Lucentis®

Non-clinical studies[1]

Established ocular pharmacokinetics comparable to Lucentis® in rabbit model (within the vitreous humor)

Comparative clinical study[1,2]

Demonstrated no clinically meaningful differences in terms of efficacy, safety, and immunogenicity, as well as pharmacokinetic and pharmacodynamic evaluation in wAMD patients (COLUMBUS-AMD Study)

CIMERLI®		Lucentis®
✓	Biological function	✓
✓	Pharmacokinetics	✓
✓	Pharmacodynamics	✓
✓	Safety profile	✓
✓	Immunogenicity	✓
✓	Drug stability	✓
✓	Drug purity	✓

1. Data on File. Coherus Biosciences, Inc. **2.** Holz FG, et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. *Ophthalmology*. 2022.

CIMERLI® (ranibizumab-eqrn) injection

IMPORTANT SAFETY INFORMATION (Continued)

WARNINGS AND PRECAUTIONS (Continued)

Neovascular (wet) age-related macular degeneration

- The ATE rate in the 3 controlled neovascular AMD studies during the first year was 1.9% (17 of 874) in the combined group of patients treated with 0.3 mg or 0.5 mg ranibizumab compared with 1.1% (5 of 441) in patients from the control arms. In the second year of Studies AMD-1 and AMD-2, the ATE rate was 2.6% (19 of 721) in the combined group of ranibizumab-treated patients compared with 2.9% (10 of 344) in patients from the control arms. In Study AMD-4, the ATE rates observed in the 0.5 mg arms during the first and second year were similar to rates observed in Studies AMD-1, AMD-2, and AMD-3
- In a pooled analysis of 2-year controlled studies (AMD-1, AMD-2, and a study of ranibizumab used adjunctively with verteporfin photodynamic therapy), the stroke rate (including both ischemic and hemorrhagic stroke) was 2.7% (13 of 484) in patients treated with 0.5 mg ranibizumab compared to 1.1% (5 of 435) in patients in the control arms (odds ratio 2.2 [95% confidence interval (0.8-7.1)])

Macular edema following retinal vein occlusion

- The ATE rate in the 2 controlled RVO studies during the first 6 months was 0.8% in both the ranibizumab and control arms of the studies (4 of 525 in the combined group of patients treated with 0.3 mg or 0.5 mg ranibizumab and 2 of 260 in the control arms). The stroke rate was 0.2% (1 of 525) in the combined group of ranibizumab-treated patients compared to 0.4% (1 of 260) in the control arms

IMPORTANT SAFETY INFORMATION (Continued)

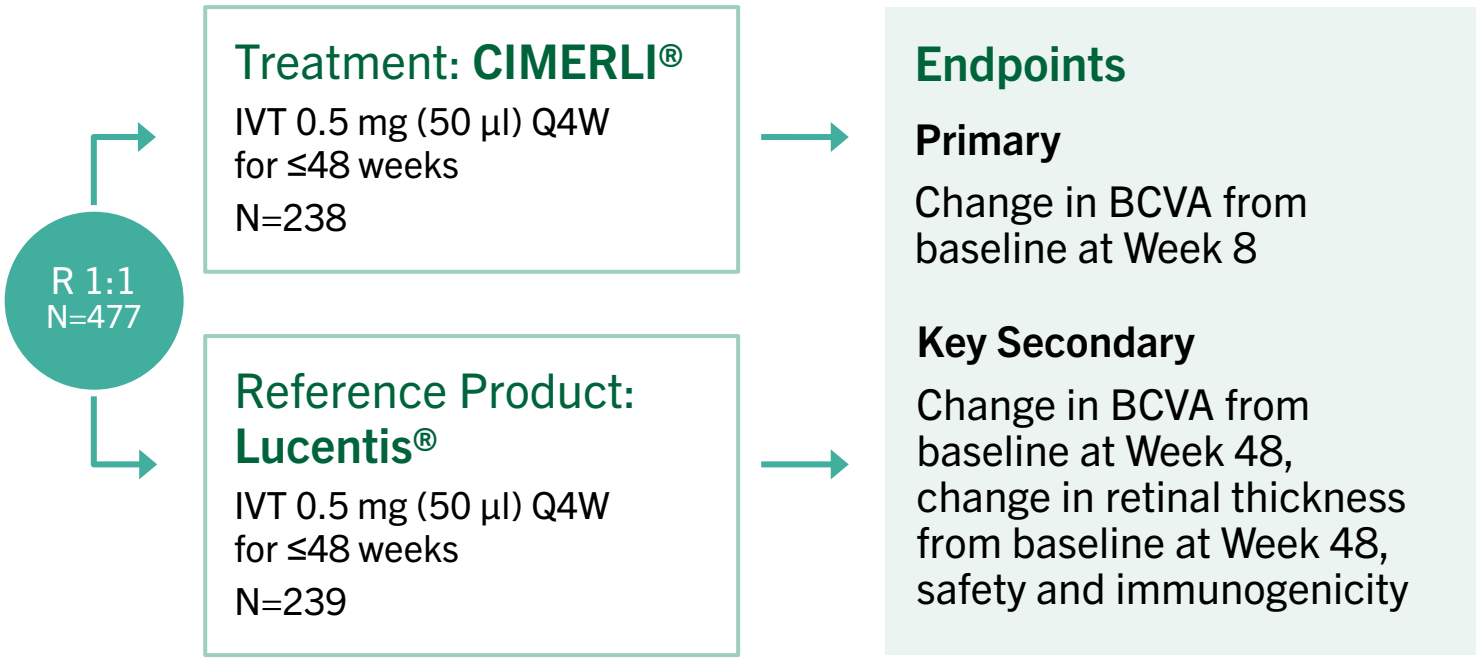
WARNINGS AND PRECAUTIONS (Continued)

Diabetic macular edema and Diabetic Retinopathy

- In a pooled analysis of Studies D-1 and D-2, the ATE rate at 2 years was 7.2% (18 of 250) with 0.5 mg ranibizumab, 5.6% (14 of 250) with 0.3 mg ranibizumab, and 5.2% (13 of 250) with control. The stroke rate at 2 years was 3.2% (8 of 250) with 0.5 mg ranibizumab, 1.2% (3 of 250) with 0.3 mg ranibizumab, and 1.6% (4 of 250) with control. At 3 years, the ATE rate was 10.4% (26 of 249) with 0.5 mg ranibizumab and 10.8% (27 of 250) with 0.3 mg ranibizumab; the stroke rate was 4.8% (12 of 249) with 0.5 mg ranibizumab and 2.0% (5 of 250) with 0.3 mg ranibizumab
- **Fatal events in patients with diabetic macular edema and diabetic retinopathy at baseline:** A pooled analysis of Studies D-1 and D-2 showed that fatalities in the first 2 years occurred in 4.4% (11 of 250) of patients treated with 0.5 mg ranibizumab, in 2.8% (7 of 250) of patients treated with 0.3 mg ranibizumab, and in 1.2% (3 of 250) of control patients. Over 3 years, fatalities occurred in 6.4% (16 of 249) of patients treated with 0.5 mg ranibizumab and in 4.4% (11 of 250) of patients treated with 0.3 mg ranibizumab. Although the rate of fatal events was low and included causes of death typical of patients with advanced diabetic complications, a potential relationship between these events and intravitreal use of VEGF inhibitors cannot be excluded

COLUMBUS-AMD Head-to-Head Study Established Clinical Equivalence Between CIMERLI® And Lucentis®[1]

- COLUMBUS-AMD was a comparative, prospective, 48-week, evaluation-masked, parallel-group, global, multicenter, randomized study in patients with treatment-naïve, subfoveal CNV due to wAMD
- Patient inclusion and exclusion criteria were well balanced between study arms:
  - ≥50 years
  - Subfoveal or juxtafoveal CNV with foveal-involving leakage related to CNV activity
  - FCP retinal thickness ≥350 µm on SD-OCT
  - Total lesion area of ≤12 MPS disc areas
  - Total CNV area ≥50% of total lesion area
  - Study eye BCVA 20/32 to 20/100



BCVA, best corrected visual acuity; CNV, choroidal neovascularization; ETDRS, Early Treatment Diabetic Retinopathy Study; FCP, foveal center point; IVT, intravitreal; MPS, macular photocoagulation study; nAMD, neovascular age-related macular degeneration; Q4W, every 4 weeks; R, randomized; SD-OCT, spectral domain optical coherence tomography.

1. Holz FG, et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. *Ophthalmology*. 2022.

CIMERLI® (ranibizumab-eqrn) injection

Baseline Patient Population And Characteristics Were Well Balanced Between CIMERLI® And Lucentis® Study Arms[1]

Patient baseline characteristics

	CIMERLI® (n=238)	Lucentis® (n=239)	Total (N=477)
Sex, female/male, no. (%)	135 (56.7)/103 (43.3)	134 (56.1)/105 (43.9)	269 (56.4)/208 (43.6)
Age (yrs), median (range)	76 (50–91)	77 (50–94)	76 (50–94)
Age group (yrs), no. (%)			
50–64	25 (10.5)	19 (7.9)	44 (9.2)
65–75	91 (38.2)	86 (36.0)	177 (37.1)
>75	122 (51.3)	134 (56.1)	256 (53.7)
Study eye, right eye, no. (%)	127 (53.4)	127 (53.1)	254 (53.2)
Study eye Snellen equivalent, no. (%)			
20/32	24 (10.1)	22 (9.2)	46 (9.6)
20/40	43 (18.1)	38 (15.9)	81 (17.0)

1. Holz FG, et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. *Ophthalmology*. 2022.

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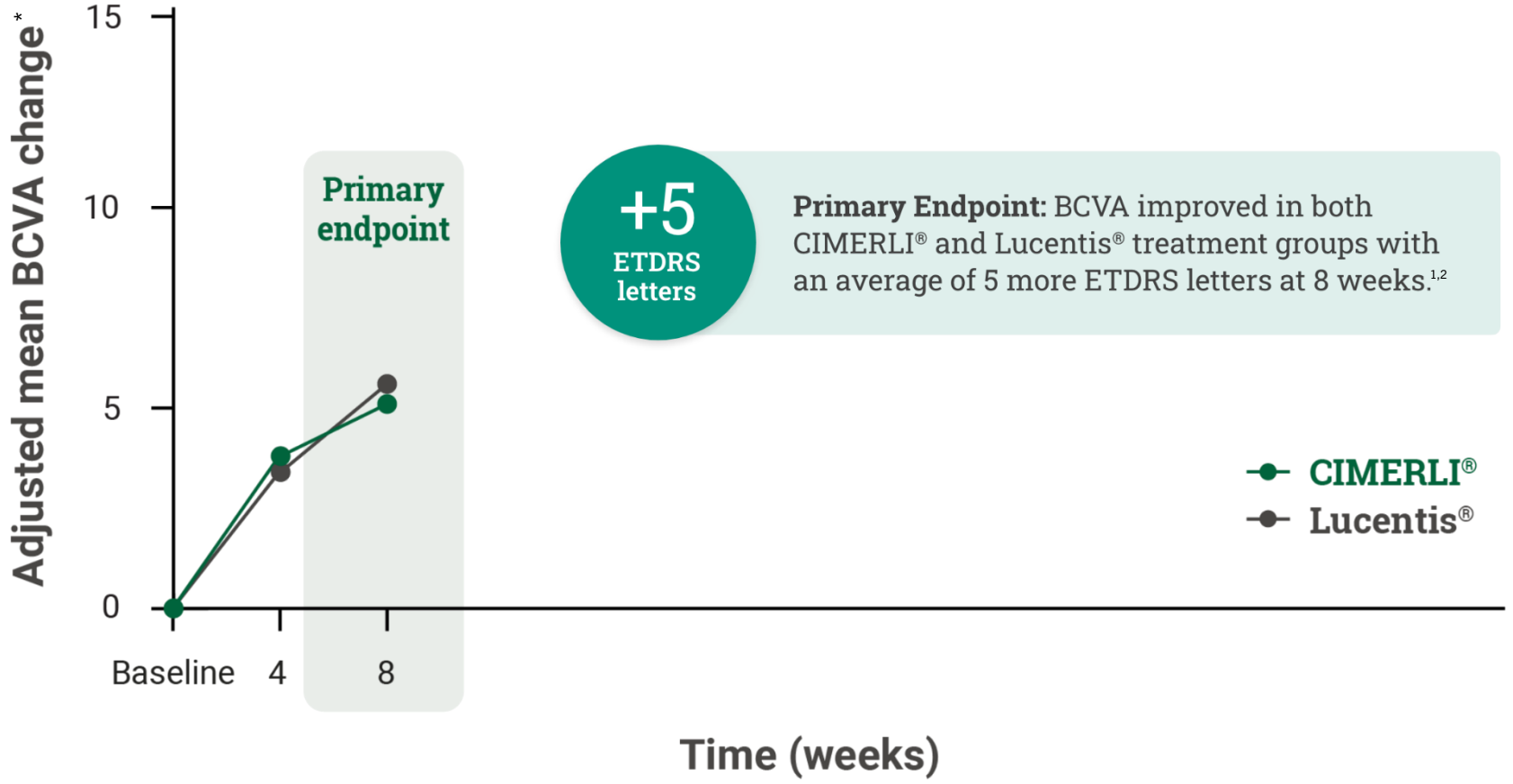
CIMERLI® Demonstrated Equivalent Efficacy To Lucentis®: Primary Endpoint At Week 8



Key Takeaway

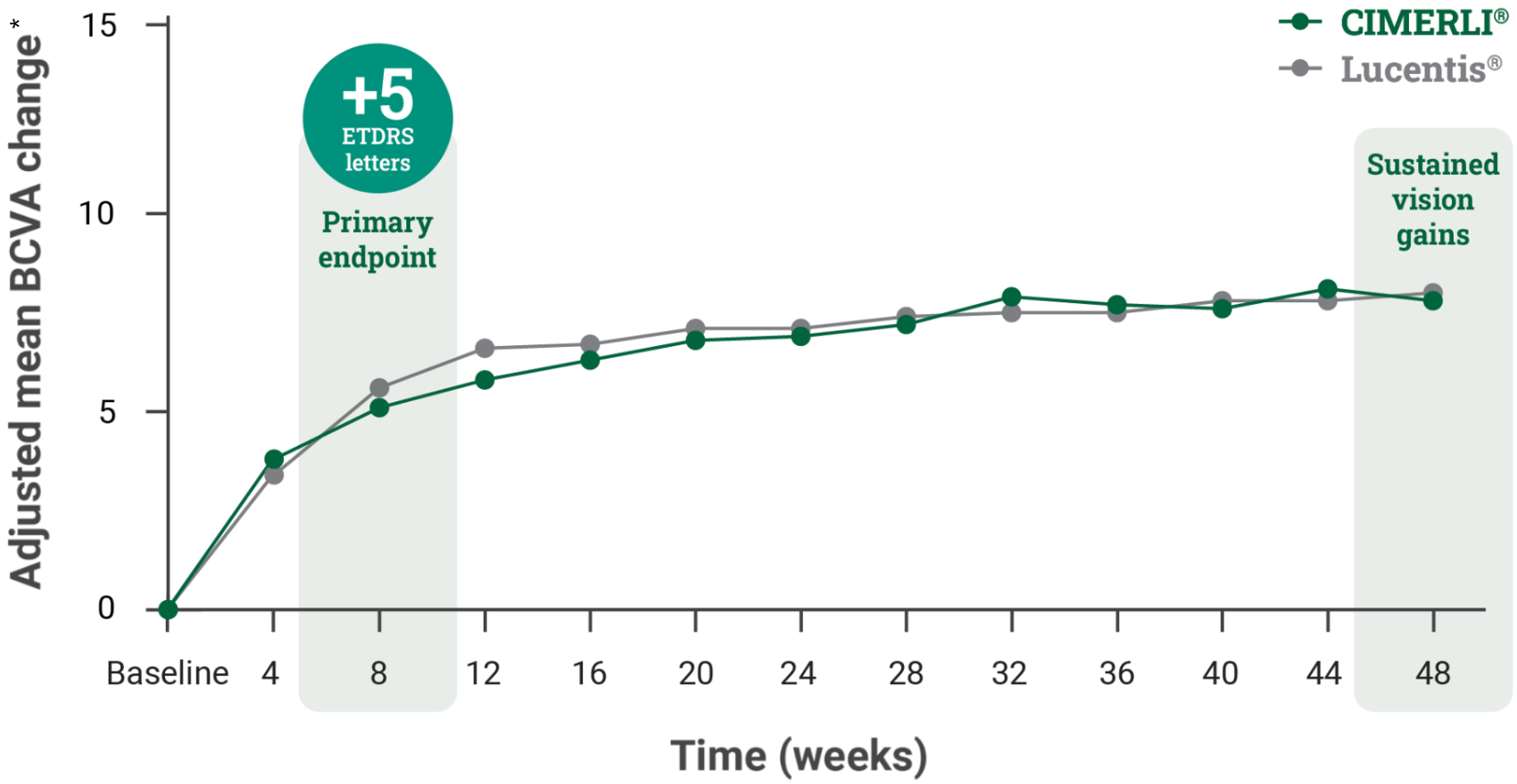
Rate of improvement in BCVA is especially steep during the initial 8-week period, clearly highlighting any difference in efficacy between products, should one exist.

*The analysis of covariance (ANCOVA) least squares mean difference for the change from baseline between CIMERLI® and Lucentis® was −0.4 ETDRS letters with a 90% confidence interval (CI) of −1.6 to 0.9, which was within the predefined equivalence margin of −3.5 to 3.5.

1. Data on File. Coherus BioSciences, Inc. **2.** Holz FG, et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. *Ophthalmology*. 2022.

CIMERLI® (ranibizumab-eqrn) injection

CIMERLI®: Proven Vision Gains At Week 8 And Sustained Through Week 48



Primary Endpoint: BCVA improved in both CIMERLI® and Lucentis® treatment groups with an average of **5 more ETDRS letters at 8 weeks.**[1,2]

Secondary Endpoint: BCVA improved in both CIMERLI® and Lucentis® treatment groups with an average of **8 more ETDRS letters at 48 weeks.**[1,2]

*The analysis of covariance (ANCOVA) least squares mean difference for the change from baseline between CIMERLI® and Lucentis® was −0.4 ETDRS letters with a 90% confidence interval (CI) of −1.6 to 0.9, which was within the predefined equivalence margin of −3.5 to 3.5.

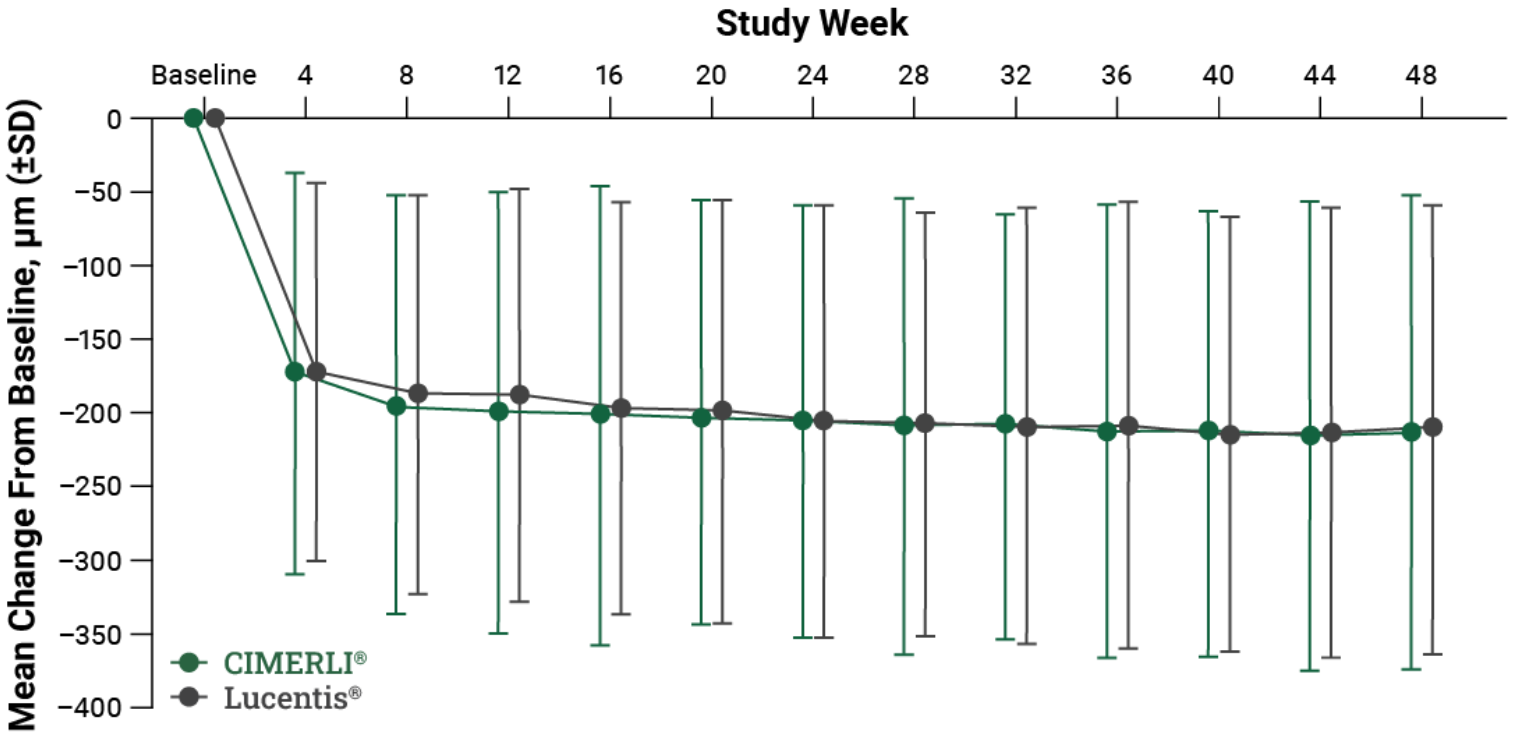
1. Data on File. Coherus BioSciences, Inc. **2.** Holz FG, et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. *Ophthalmology*. 2022.

CIMERLI® (ranibizumab-eqrn) injection

CIMERLI® Sustained Reduction in Retinal Thickness Through Week 48

Secondary Endpoint:

Mean reduction in foveal center point (FCP) thickness at Week 48 from baseline of **213.3 µm CIMERLI®** and **211.0 µm Lucentis®**.[1]



1. Holz FG et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. *Ophthalmology*. 2022.

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CIMERLI® Demonstrated A Comparable Safety Profile To Lucentis® At Week 48[1]

Most frequently observed drug-related adverse events (AEs)		
Adverse Reaction	CIMERLI® % (n=238)	Lucentis® % (n=239)
Cataract	0.0% (0)	2.1% (5)
Retinal Pigment Epithelium Tear	0.4% (1)	1.3% (3)
Reduced Visual Acuity	0.0% (0)	1.3% (3)
Vitreous Hemorrhage	0.4% (1)	0.4% (1)
Eye Pain	0.8% (2)	0.0% (0)
Increased Gamma-Glutamyl Transferase Level	0.4% (1)	0.8% (2)
Increased Intraocular Pressure	1.3% (3)	0.8% (2)
Intraocular Inflammation*	**0.8% (2)**	**0.8% (2)**

*Among CIMERLI® patients, one case of iridocyclitis and one case of conjunctivitis were observed; two cases of punctuate keratitis were observed among Lucentis® patients.

1. Holz FG, et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. *Ophthalmology*. 2022.

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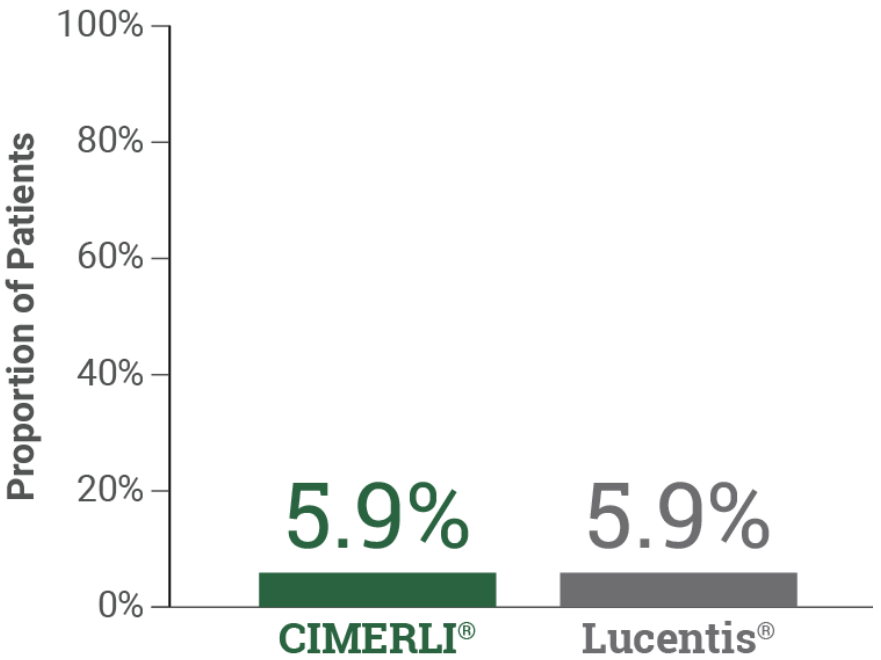
CIMERLI® Demonstrated An Immunogenicity Profile Comparable To Lucentis®[1]

- Few patients developed anti-drug antibodies (ADA) during the study and had similar levels of ADA titers across treatment arms*
- No neutralizing antibodies (NAbs) were detected up to Week 24, one patient tested positive for NAbs up to Week 48 (CIMERLI®)

*The clinical significance of immunoreactivity to ranibizumab is unclear at this time.

Incidence of Anti-Drug Antibodies (ADAs)



1. Holz FG, et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. *Ophthalmology*. 2022.

CIMERLI® (ranibizumab-eqrn) injection

CIMERLI® Is The First And Only FDA-Approved Biosimilar Interchangeable With Lucentis®[1,2]

Totality of Evidence

CIMERLI® demonstrated biosimilarity to Lucentis®

With these additional factors to support interchangeability:

- ✓ CIMERLI® is a product with relatively low complexity [eg. no glycosylation]
- ✓ CIMERLI® has low incidence of immunogenicity (along with no history of ranibizumab inducing severe immune responses)
- ✓ CIMERLI®-related serious adverse events were comparable to Lucentis®

When alternating or switching between CIMERLI® and Lucentis®:

- Risk of clinically impactful immunogenic response from systemic anti-drug antibodies does not increase
- Risk of intraocular inflammation is expected to be consistent with ranibizumab product use

Be confident CIMERLI® can be substituted for Lucentis® in any given patient.

1. CIMERLI® (ranibizumab-eqrn) prescribing information. Redwood City, CA: Coherus BioSciences, Inc. **2.** Considerations in Demonstrating Interchangeability with a Reference Product: Guidance for Industry. US Food and Drug Administration. https://www.fda.gov/media/124907/download. Published 2019. Accessed on April 27, 2023.

CIMERLI® (ranibizumab-eqrn) injection

Summary

COLUMBUS-AMD study established clinical biosimilarity of CIMERLI® to Lucentis®

CIMERLI® demonstrated clinical equivalence to reference product Lucentis® in patients with newly diagnosed nAMD, in terms of:

- Clinical efficacy
- Safety (local and systemic)
- Immunogenicity

CIMERLI®, an FDA-approved interchangeable ranibizumab biosimilar, serves as a treatment option for patients with:

- Neovascular (wet) AMD
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)
- Myopic choroidal neovascularization (mCNV)

CIMERLI® (ranibizumab-eqrn) injection

IMPORTANT SAFETY INFORMATION (Continued)

ADVERSE REACTIONS

- Serious adverse events related to the injection procedure have occurred in <0.1% of intravitreal injections, including endophthalmitis, rhegmatogenous retinal detachment, and iatrogenic traumatic cataract.
- In ranibizumab-treated patients compared with the control group, the most common ocular side effects included conjunctival hemorrhage, eye pain, vitreous floaters, and intraocular pressure. The most common non-ocular side effects included nasopharyngitis, anemia, nausea, and cough.
- As with all therapeutic proteins, there is the potential for an immune response in patients treated with ranibizumab. The clinical significance of immunoreactivity to ranibizumab is unclear at this time

IMPORTANT SAFETY INFORMATION (Continued)

Postmarketing Experience

The following adverse reaction has been identified during post-approval use of ranibizumab products:

- Ocular: Tear of retinal pigment epithelium among patients with neovascular AMD

To report SUSPECTED ADVERSE REACTIONS, contact Coherus BioSciences at 1-800-483-3692 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see CIMERLI® Prescribing Information.