Bausch + Lomb Announces Publication of enVista Envy™ Full Range of Vision Intraocular Lens Pivotal U.S. Clinical Trial

- enVista Envy full range of vision intraocular lens (IOL) met all primary efficacy and safety endpoints in multicenter study
- Results show that enVista Envy IOLs deliver excellent visual performance, good contrast sensitivity and a favorable dysphotopsia profile

VAUGHAN, Ontario, Sept. 11, 2025 – Bausch + Lomb Corporation (NYSE/TSX: BLCO), a leading global eye health company dedicated to helping people see better to live better, today announced that the *American Journal of Ophthalmology* has published results of the pivotal U.S. clinical trial of the enVista Envy novel full visual range intraocular lens. The study compared visual, refractive and patient-reported outcomes following implantation of enVista Envy and the enVista® monofocal IOL in cataract surgery patients.

"enVista Envy has been well received as the first premium IOL on the widely used enVista platform," said Luc Bonnefoy, president, Surgical, Bausch + Lomb. "Results of this study confirm the advantages that this lens offers – continuous range of vision from distance to near with excellent dysphotopsia tolerance."

In the multicenter, prospective, masked, controlled trial, investigators randomized 501 cataract patients into two groups, one of which received bilateral implantation of the enVista Envy (n= 332) while the other received the enVista monofocal IOL (MX60E) (n= 169). Primary efficacy endpoints included monocular corrected distance visual acuity (CDVA, 4m), distance-corrected intermediate (DCIVA, 66cm) and near (DCNVA, 40cm) visual acuity. Investigators also measured binocular DCIVA, DCNVA uncorrected intermediate (UIVA), and near visual acuity (UNVA) postoperatively (day 120-180). Primary safety endpoints included adverse events and serious adverse events, as well as surgical interventions related to the optical properties of the IOL through the same postoperative period.

Key Results

- The study met all primary efficacy endpoints, with Envy demonstrating non-inferiority for monocular CDVA and statistical superiority for monocular DCIVA and DCNVA over the monofocal group.
- The Envy group also had better binocular UIVA, DCIVA, UNVA and DCNVA compared to the monofocal group (all $p<0.0001$).
- Envy demonstrated consistent visual acuity of ~0.1 logMAR from -1.50 to -2.50 D.
- The difference in mesopic contract sensitivity (without glare) between the two groups was less than the minimum detectable difference of 0.15 logCS.
- The study met all primary safety endpoints, with no treatment-emergent serious adverse events related to the study lens, no secondary surgical interventions due to the lens' optical properties and no cumulative or persistent adverse events.

"Trial results mirror what I have seen in my practice," said Mitchell Shultz, medical director, Shultz-Chang Vision in Northridge, CA, and the study's lead author. "I have long relied on the enVista platform, and I will continue to rely on Envy as an excellent option for cataract patients seeking an IOL that can

provide a full range of vision with minimal visual disturbances, as well as precision astigmatism correction."

enVista Envy delivers outstanding performance in all lighting conditions thanks to ActivSync Optic intelligent energy distribution, which optimizes vision in many lighting conditions. Although not evaluated in this trial, the Envy toric IOL allows surgeons to address a broader range of astigmatic patients with greater accuracy and precision, offering 0.50D increments and the ability to treat under 1.0D of corneal astigmatism.

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enVista Envy toric and non-toric IOL Indications and Important Safety Information
Indications

The **enVista Envy hydrophobic acrylic IOL** is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia with less than or equal to 1.0 D preoperative corneal astigmatism following removal of a cataractous lens to mitigate the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity to an aspheric monofocal IOL.

The **enVista Envy toric hydrophobic acrylic IOL** is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia and corneal astigmatism following removal of a cataractous lens to mitigate the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity to an aspheric monofocal IOL.

Warnings/Precautions
Physicians should weigh the potential risk/benefit ratio before implanting the enVista Envy lens under any of the circumstances or conditions outlined in the Instructions for Use labeling. Some visual disturbances may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or radial lines around point sources of light (starbursts) under nighttime conditions, glare, double vision, haziness and blurred vision. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions such as nighttime driving. As with other trifocal IOLs, there is a possibility that visual disturbances may be significant enough that the patient will request explant of the IOL. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients, therefore, patients implanted with trifocal IOLs should exercise caution when driving at night or in low light or poor visibility conditions. Care should be taken to achieve IOL centration as IOL decentration may result in patients experiencing visual disturbances or suboptimal vision under certain lighting conditions. The surgeon must target emmetropia to achieve optimal visual performance. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). Please provide a copy of the Patient Information Brochure, which can be found at www.bausch.com/IFU. Posterior capsule opacification (PCO) may significantly affect the vision of patients with multifocal IOLs earlier in its progression than patients with monofocal IOLs. This may be due to the reduced contrast sensitivity observed with multifocal IOLs.

Additional Precautions for Toric IOLs: The enVista Envy Toric IOL has not been evaluated in a clinical study. In general, astigmatism that is corrected with a higher cylinder power IOL can result in clinically

significant residual astigmatism. The effect of residual astigmatism at distance, intermediate, and near was evaluated in a clinical study of patients who had been implanted with non-toric enVista Envy IOLs and were induced with cylinder power to simulate various levels of residual astigmatism. If a secondary surgical intervention is necessary to reposition the IOL, explantation should be considered as some patients may have recurrent or persistent issues related to rotational instability and misalignment.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

ATTENTION: See the Directions for Use for a complete listing of indications and important safety information.

About Bausch + Lomb

Our mission is simple – we help people see better to live better, all over the world. For nearly two centuries we've evolved with the changing needs of patients and customers, and our commitment to innovation and improving the standard of care in eye health has never been stronger. From contact lenses to prescription products, over-the-counter options, surgical devices and more, we're turning bold ideas into better outcomes through passion, perseverance and purpose. Learn more at www.bausch.com and connect with us on Facebook, Instagram, LinkedIn, X and YouTube.

References

1. Shultz, M et al. Visual and patient-reported outcomes of a novel full visual range IOL versus a monofocal IOL: A randomized multicenter US trial. *Am. J. Ophthlamol. DOI: 10.1016/j.ajo.2025.08.050*

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