Samsung Bioepis and Harrow Present Interim Data from a Large-Scale Post-Marketing Surveillance Study on SB11 (BYOOVIZ® / AMELIVU®), a Biosimilar to Lucentis (ranibizumab), at ASRS 2026

July 20, 2026

- ***A real-world PMS study based on a large population demonstrates comparable safety profile of SB11 (BYOOVIZ® / AMELIVU®) to reference ranibizumab***
- ***In treatment-naïve patients, SB11 provided functional and anatomical improvements, while BCVA and CST were well maintained in patients who were switched from other anti-VEGF treatments to SB11, adding clinical confidence in using SB11***

INCHEON, Korea and NASHVILLE, Tenn., July 20, 2026 (GLOBE NEWSWIRE) -- Samsung Bioepis Co., Ltd. and Harrow (Nasdaq: HROW), a leading provider of ophthalmic disease management solutions in North America, presented interim data from a post-marketing surveillance (PMS) study on SB11 (US brand name: BYOOVIZ®, Korea brand name: AMELIVU®), a biosimilar referencing Lucentis[1], at the 44th Annual Meeting of the American Society of Retina Specialists (ASRS), held in Montréal, Canada, July 15–18, 2026.

“The interim results from this large-scale post-marketing surveillance study reinforce the comparable safety profile of SB11 to reference ranibizumab. Importantly, the study demonstrated clinically meaningful efficacy improvement in treatment-naïve patients while maintaining efficacy in those switched from other anti-VEGF therapies,” said Donghoon Shin, Executive Vice President and Head of Clinical Sciences Division, Samsung Bioepis. "At Samsung Bioepis, we are committed to generating robust real-world evidence that can support retinal specialists in making informed treatment decisions for their patients."

"We believe this post-marketing surveillance data further strengthens the clinical foundation supporting BYOOVIZ, reinforcing the confidence retina specialists can have in this biosimilar option — both in treatment-naïve patients and those transitioning from other anti-VEGF therapies," said Mark L. Baum, Chief Executive Officer of Harrow. "We're grateful for our collaboration with Samsung Bioepis in generating this evidence, and we remain committed to giving physicians the data they need to prescribe with confidence."

This open-label, prospective, multicenter, observational, Phase 4 PMS study, initiated in May 2022 and completed in May 2026, was designed to evaluate real-world safety and efficacy data for SB11 by evaluating a large patient population from a PMS study conducted in Republic of Korea. The interim report includes data from 298 patients (182 treatment-naïve, 116 switched) out of 305 patients who had been enrolled in the study as of the interim data cutoff. To reflect real-world practice, treatment interval was determined at the investigator’s discretion, and the study followed up with patients up to 24 weeks after the first dose. Efficacy was assessed by best-corrected visual acuity (BCVA) and central subfield thickness (CST), with subgroup analyses by treatment status (naïve/switched). Safety was evaluated by the incidence of adverse events.

The mean (standard deviation; SD) BCVA improved by -0.10 (0.29) in the treatment-naïve patients and -0.03 (0.24) in switched patients (P= 0.0239). Mean (SD) CST improved by -95 (125) μm in the treatment-naïve patients and -53 (108) μm in switched patients (P= 0.0168). Across different indications, there was no statistically significant difference in BCVA (P=0.6312) and CST (P=0.1686) outcome. In contrast, disease duration was significantly associated with BCVA (P= 0.0003) and CST (P=0.001) outcomes, suggesting that earlier treatment may lead to a better visual prognosis. No new safety concerns were identified.

Title: Efficacy and Safety of SB11 in Treatment-Naïve and Switched Patients with Retinal Diseases: Interim Results from a Post-Marketing Surveillance Study
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Presentation Type: paper on demand (Category: POD 1: AMD – Neovascular)

About BYOOVIZ

BYOOVIZ (ranibizumab-nuna) injection, for intravitreal use is a biosimilar to LUCENTIS (ranibizumab injection)

INDICATIONS AND USAGE

BYOOVIZ, 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)
- Myopic Choroidal Neovascularization (mCNV)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Ocular or periocular infections
- Hypersensitivity

WARNINGS AND PRECAUTIONS

- Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients should be monitored following the injection
- Increases in intraocular pressure (IOP) have been noted both pre- and post intravitreal injection
- There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors

ADVERSE REACTIONS

- The most common adverse reactions (reported more frequently in ranibizumab treated subjects than control subjects) are conjunctival hemorrhage, eye pain, vitreous floaters, and increased IOP

Please see full Prescribing information

About Samsung Bioepis Co., Ltd.

Established in 2012, Samsung Bioepis is a biopharmaceutical company committed to realizing healthcare that is accessible to everyone. Through innovations in product development and a firm commitment to quality, Samsung Bioepis aims to become the world's leading biopharmaceutical company. Samsung Bioepis continues to advance a broad pipeline of biologic candidates that cover a spectrum of therapeutic areas, including immunology, oncology, ophthalmology, hematology, nephrology, neurology, and endocrinology. For more information, please visit www.samsungbioepis.com and follow us on LinkedIn and X.

About Harrow

Harrow, Inc. (Nasdaq: HROW) is a leading provider of ophthalmic disease management solutions in North America, offering a comprehensive portfolio of products that address conditions affecting both the front and back of the eye, such as dry eye disease, wet (or neovascular) age-related macular degeneration, cataracts, refractive errors, glaucoma and a range of other ocular surface conditions and diseases of the retina. Harrow was founded with a commitment to deliver safe, effective, accessible, and affordable medications that enhance patient compliance and improve clinical outcomes. For more information about Harrow, please visit harrow.com and connect with us on LinkedIn.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered such “forward-looking statements.” Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ from those predicted include, among others, risks related to: liquidity or results of operations; our ability to successfully implement our business plan, develop and commercialize our products, product candidates and proprietary formulations in a timely manner or at all, identify and acquire additional products, manage our pharmacy operations, service our debt, obtain financing necessary to operate our business, recruit and retain qualified personnel, manage any growth we may experience and successfully realize the benefits of our previous acquisitions and any other acquisitions and collaborative arrangements we may pursue; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions, including inflation and supply chain challenges; regulatory and legal risks and uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general, including the ongoing communications with the U.S. Food and Drug Administration relating to compliance and quality plans at our outsourcing facility in New Jersey; physician interest in and market acceptance of our current and any future formulations and compounding pharmacies generally. These and additional risks and uncertainties are more fully described in Harrow’s filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2025, and other filings

with the SEC. Such documents may be read free of charge on the SEC's web site at sec.gov. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Except as required by law, Harrow undertakes no obligation to update any forward-looking statements to reflect new information, events, or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

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[1] Lucentis is a trademark of Genentech.