Harrow Announces Commercial Launch of BYOOVIZ® in the United States

July 1, 2026

Expands Harrow's Growing Retina Portfolio with an Interchangeable Ranibizumab Biosimilar

NASHVILLE, Tenn., July 01, 2026 (GLOBE NEWSWIRE) -- Harrow (Nasdaq: HROW), a leading provider of ophthalmic disease management solutions in North America, today announced the commercial launch of BYOOVIZ® (ranibizumab-nuna), an FDA-approved biosimilar referencing LUCENTIS[i] (ranibizumab) and developed by Samsung Bioepis Co., Ltd.

The launch follows Harrow's exclusive U.S. commercialization agreement with Samsung Bioepis, one of the world's leading biosimilar developers and manufacturers. Through this partnership, Harrow obtained exclusive U.S. rights to commercialize BYOOVIZ and OPUVIZ® (aflibercept-yszy), an FDA-approved biosimilar referencing EYLEA[ii] (aflibercept), further strengthening the Company's position in the rapidly growing retinal biologics market.

BYOOVIZ was approved by the U.S. Food and Drug Administration (FDA) as the first ophthalmology biosimilar in the U.S. for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), and Myopic Choroidal Neovascularization (mCNV). As an FDA-designated interchangeable biosimilar to LUCENTIS, BYOOVIZ provides retina specialists with a clinically proven anti-VEGF therapy that offers confidence, flexibility, and choice in patient care.

The launch of BYOOVIZ marks another important step in the evolution of Harrow's market-leading retina franchise. With an estimated $9 billion U.S. anti-VEGF market[iii] and increasing demand for therapies that treat sight-threatening retinal diseases, Harrow continues to build a differentiated portfolio of buy-and-bill products designed specifically for the needs of retina specialists and the patients they serve.

BYOOVIZ joins Harrow's expanding retina franchise, which includes IHEEZO® (chloroprocaine hydrochloride 3% ophthalmic gel), a branded FDA-approved ocular anesthetic indicated for ocular surface anesthesia that is increasingly utilized by retina specialists during intravitreal injection procedures, and TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/ml, a high-trust preservative-free injectable corticosteroid, broadly labeled and increasingly used by retina specialists nationwide. Together, these products enable Harrow to support both the procedural and therapeutic aspects of retinal disease management, providing retina practices with a trusted commercial partner across multiple points of care.

"BYOOVIZ is far more than a product launch—it underscores Harrow's commitment to the U.S. retina community," said Mark L. Baum, Founder, Chairman, and Chief Executive Officer of Harrow. "Over the past several years, we have earned the trust of physicians through products like IHEEZO and TRIESENCE—products a growing number of retina specialists have integrated into their procedural workflows—supported by one of the most experienced and tenured retina teams in the industry. The investments we've made in our commercial infrastructure are specifically designed to serve retina specialists, and we intend to keep investing in and growing our retina franchise for years to come. With BYOOVIZ, we will bring our customers an interchangeable ranibizumab biosimilar to a market increasingly focused on both clinical confidence and economic value. Together with exclusive commercialization rights to OPUVIZ in the US, we believe we are creating one of the most compelling retina portfolios in ophthalmology."

“The introduction of BYOOVIZ gives retina specialists another valuable treatment option for our patients,” said Samuel A. Minaker, M.D., vitreoretinal surgeon, Director of Clinical Research at Tyler Retina Consultants. “Many of my patients are treated with LUCENTIS or a LUCENTIS-referenced biosimilar; however, we have found that access to supply has not always been assured, with products coming in and out of availability more recently. What gives me additional confidence in BYOOVIZ is its interchangeability designation, supported by data showing no clinically meaningful differences between the biosimilar and reference product when patients switch between therapies. Just as importantly, it's exciting to see this product return to the market through a commercial partner like Harrow that has already earned credibility in my practice and within the retina community. Harrow understands the needs of retina practices, has demonstrated a commitment to supporting physicians and patients, and brings a level of confidence that makes BYOOVIZ a welcome addition to the treatment options available for my patients.”

“I’ve had the opportunity to work with Harrow on several ophthalmic products,” said Seenu M. Hariprasad, M.D., Chair of Ophthalmology and Visual Science, Chief of Vitreoretinal Service, and Shui-Chin Lee Professor of Ophthalmology and Visual Science at the University of Chicago Medicine. “I first worked with Harrow through IHEEZO, which helped improve the patient experience during intravitreal injection procedures, and later with TRIESENCE, an important treatment option for many patients. Throughout that time, their team has demonstrated an understanding of the clinical, operational, and economic realities retina specialists face every day. Adding BYOOVIZ to their portfolio is a natural extension of that experience. Having access to a trusted

ranibizumab biosimilar from a company with experience supporting retina specialists makes BYOOVIZ a welcome addition to the treatment options available for patients."

Physician Prescribing Information

Healthcare providers interested in prescribing BYOOVIZ (ranibizumab-nuna) for their patients can access prescribing information, patient support resources, and ordering details by visiting https://www.byooviz.com or by calling 1-833-4HARROW (442-7769).

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 PRECATIONS

- 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

OPUVIZ® (aflibercept-yszy) injection, for intravitreal use is a biosimilar to EYLEA (aflibercept)

INDICATIONS AND USAGE
OPUVIZ is a vascular endothelial growth factor (VEGF) inhibitor 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)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Ocular or periocular infections
- Active intraocular inflammation
- Hypersensitivity

WARNINGS AND PRECATIONS

- Endophthalmitis, retinal detachments, and retinal vasculitis with or without occlusion may occur following intravitreal injections. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection.
- There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.

ADVERSE REACTIONS

- The most common adverse reactions (≥5%) reported in patients receiving aflibercept were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

Please see full Prescribing information

IHEEZO (chloroprocaine hydrochloride ophthalmic gel) 3%, for topical ophthalmic use

INDICATIONS AND USAGE

IHEEZO is an ester anesthetic indicated for ocular surface anesthesia.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- IHEEZO is contraindicated in patients with a history of hypersensitivity to any component of this preparation

WARNINGS AND PRECATIONS

- Not for Injection or Intraocular Administration.
- Corneal Injury Due to Insensitivity.
- Corneal Opacification
- For Administration by Healthcare Provider: IHEEZO is not intended for patient self-administration

ADVERSE REACTIONS

- Most common adverse reaction is mydriasis (approximately 25%)

Please see full Prescribing information

TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/mL

INDICATIONS AND USAGE
TRIESENCE® Suspension is indicated for:

- Treatment of the following ophthalmic diseases: sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids.
- Visualization during vitrectomy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- TRIESENCE® Suspension is contraindicated in patients with systemic fungal infections.
- TRIESENCE® Suspension is also contraindicated in patients with hypersensitivity to corticosteroids or any component of TRIESENCE® Suspension. Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroid therapy.

WARNINGS AND PRECATIONS

- TRIESENCE® is a suspension; it should not be administered intravenously.
- Ophthalmic effects: May include cataracts, infections, and glaucoma. Monitor intraocular pressure.
- Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome and hyperglycemia: Monitor patients for these conditions and taper doses gradually.
- Infections: Increased susceptibility to new infection and increased risk of exacerbation, dissemination, or reactivation of latent infection.
- Elevated blood pressure, salt and water retention, and hypokalemia: Monitor blood pressure and sodium, potassium serum levels.
- GI perforation: Increased risk in patients with certain GI disorders.
- Behavioral and mood disturbances: May include euphoria, insomnia, mood swings, personality changes, severe depression, and psychosis.
- Decreases in bone density: Monitor bone density in patients receiving long term corticosteroid therapy.
- Live or live attenuated vaccines: Do not administer to patients receiving immunosuppressive doses of corticosteroids.
- Negative effects on growth and development: Monitor pediatric patients on long-term corticosteroid therapy.
- Use in pregnancy: Fetal harm can occur with first trimester use.
- Weight gain: May cause increased appetite.

ADVERSE REACTIONS

- Based on a review of the available literature, the most commonly reported adverse events following ocular administration of triamcinolone acetonide were elevated intraocular pressure and cataract progression. These events have been reported to occur in 20-60% of patients.
- Less common reactions occurring in up to 2% of patients include: endophthalmitis (infectious and non-infectious), hypopyon, injection site reactions (described as blurring and transient discomfort), glaucoma, vitreous floaters, detachment of retinal pigment epithelium, optic disc vascular disorder, eye inflammation, conjunctival hemorrhage and visual acuity

reduced. Cases of exophthalmos have also been reported.

Please see full Prescribing information

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.

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. As a wholly owned subsidiary of Samsung Epis Holdings, Samsung Bioepis continues to advance a broad pipeline of biologic candidates that cover a spectrum of therapeutic areas, including immunology, oncology, ophthalmology, hematology, nephrology, endocrinology and neurology. For more information, please visit www.samsungbioepis.com and follow us on LinkedIn and X.

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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[i] Lucentis is a trademark of Genentech, Inc.

[ii] Eylea is a trademark of Regeneron Pharmaceuticals, Inc

[iii] Emergen Research, U.S. Anti-VEGF Market Size, Growth Outlook 2034