Harrow Acquires U.S. Commercial Rights to BYQLOVI™ (Clobetasol Propionate Ophthalmic Suspension) 0.05% from Formosa Pharmaceuticals

June 9, 2025

NASHVILLE, Tenn. & TAIPEI, Taiwan--(BUSINESS WIRE)--Jun. 9, 2025-- Harrow (Nasdaq: HROW), a leading North American eyecare pharmaceutical company, and Taiwan-based Formosa Pharmaceuticals ("Formosa", 6838.TW), today announced a licensing agreement, whereby Harrow has acquired the exclusive U.S. commercial rights for BYQLOVI™ (clobetasol propionate ophthalmic suspension) 0.05%. BYQLOVI was recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of post-operative inflammation and pain following ocular surgery and is the first new ophthalmic steroid in its class in over 15 years. Harrow expects BYQLOVI to be available in the fourth quarter of 2025.

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"We are thrilled to soon launch BYQLOVI, a truly clinically differentiated topical corticosteroid, into a U.S. market that now exceeds 7 million annual ophthalmic surgeries," said Mark L. Baum, Chief Executive Officer of Harrow. "With compelling efficacy, extraordinary safety, and patient-friendly dosing, BYQLOVI has the potential to shift the paradigm in the multi-billion-dollar U.S. post-surgical care ophthalmic segment."

"Harrow's commitment to innovation, patient access, and physician engagement closely aligns with our mission to promote unique clinical advancements that improve patient outcomes," said Erick Co, President and CEO of Formosa Pharmaceuticals. "We are confident that Harrow's leadership in the U.S. eyecare space will ensure BYQLOVI's successful adoption among surgeons and eyecare professionals – and ultimately, better post-surgical experiences for U.S. patients."

BYQLOVI, a high-potency ophthalmic corticosteroid formulated using Formosa's proprietary APNT® nanoparticle formulation technology, delivers a highly uniform suspension that minimizes particle setting and provides consistent dosing. Its pharmacologic performance and clinical outcomes position it as a best-in-class option for post-operative inflammation and pain.

Key highlights of BYQLOVI include:

Best-in-Class Pain Relief with 77% and 85%, respectively, of patients in supportive pivotal clinical studies reporting no pain at Day 4 post-surgery; 82% and 87%, respectively, reporting no pain at Day 8 post-surgery.

Best-in-Class Inflammation Clearance with 33% and 30%, respectively, of patients in supportive pivotal clinical studies with zero cell counts in the anterior chamber at Day 8 post-surgery.

Safety Benefits with only 1.4% of patients experiencing elevated intraocular pressure (IOP), a substantially lower rate compared to other ophthalmic steroids.

Best-in-Class Post-Surgical Dosing at 1 drop BID dosing for 14 days on label; without the need for a loading dose and a maintenance phase.

About BYQLOVI™ (clobetasol propionate ophthalmic suspension) 0.05%

BYQLOVI (clobetasol propionate ophthalmic suspension) 0.05%, for topical ophthalmic use

INDICATIONS AND USAGE

BYQLOVI is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

CONTRAINDICATIONS

BYQLOVI is contraindicated in most active viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

WARNINGS AND PRECAUTIONS

Intraocular Pressure (IOP) Increase: Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, IOP should be monitored.

Cataracts: Prolonged use of corticosteroids may result in posterior subcapsular cataract formation.

Delayed Healing: The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Corneal and Scleral Melting: In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and where appropriate, fluorescein staining.

Bacterial Infections: Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated.

Viral Infections: Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungal Infections: Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

ADVERSE REACTIONS

Ocular adverse reactions occurring in ≥ 1% of subjects in clinical studies who received BYQLOVI included eye inflammation (2%), corneal edema (2%), anterior chamber inflammation (2%), cystoid macular edema (2%), intraocular pressure elevation (1%), photophobia (1%) and vitreous detachment (1%). Many of these reactions may have been the consequence of the surgical procedure.

USE IN SPECIAL POPULATIONS

Pregnancy. There are no adequate and well-controlled studies of BYQLOVI administration in pregnant women to inform a drug-associated risk.

For additional information about BYQLOVI™, please see the Full Prescribing Information.

About Formosa Pharmaceuticals

Formosa Pharmaceuticals, Inc. (6838.TW) is a clinical stage biotechnology company with primary focus in the areas of ophthalmology and oncology. The company's proprietary nanoparticle formulation technology (APNT®), through which BYQLOVI was developed, improves the dissolution and bioavailability of APIs for topical, oral, and inhaler administration. Resulting formulations have high uniformity, purity, and stability, thereby allowing the utilization of poorly soluble or extremely potent drug agents which otherwise may face insurmountable challenges in safety, delivery, and penetration to target tissues. For more details about Formosa Pharma and APNT®, visit www.formosapharma.com.

About Harrow

Harrow, Inc. (Nasdaq: HROW) is a leading eyecare pharmaceutical company engaged in the discovery, development, and commercialization of innovative ophthalmic pharmaceutical products for the North American market. Harrow helps eyecare professionals preserve the gift of sight by making its portfolio of pharmaceutical products accessible and affordable to millions of patients each year. For more information about Harrow, please visit harrow.com.

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, including litigation matters, and other uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general; 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, 2023, subsequent Quarterly Reports on Form 10-Q, 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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