Harrow Relaunches TRIESENCE®

October 3, 2024

NASHVILLE, Tenn.--(BUSINESS WIRE)--Oct. 3, 2024-- Harrow (Nasdaq: HROW), a leading North American eyecare pharmaceutical company, announced the relaunch of TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/mL, a preservative-free synthetic corticosteroid that is approved by the U.S. Food and Drug Administration (FDA) for visualization during vitrectomy and for the treatment of ocular inflammatory conditions that are unresponsive to topical corticosteroids.

In commenting on the announcement, Mark L. Baum, Chairman and Chief Executive Officer of Harrow, said, “We are very excited to have brought TRIESENCE back to the U.S. market, providing ophthalmologists access to a trusted FDA-approved product that has benefited millions of Americans. Accomplishing this required rebuilding the entire TRIESENCE supply chain and involved a global collaboration between Harrow and technical experts from our partners around the world. We are grateful for this team’s dedication and commitment, without which we would not have achieved this success.”

In response to Harrow’s relaunch of TRIESENCE, Dr. Rishi Singh, MD, an ophthalmologist and vitreoretinal surgeon of Cleveland Clinic Florida, remarked, “An FDA-approved, preservative-free corticosteroid is critical for office-based and surgical procedures. TRIESENCE is a pharmaceutically elegant injectable suspension that appears as a white backdrop against the back of the retina, enabling a higher degree of visibility of the vitreous and pathologic membranes during vitrectomy. It has long been a trusted, indispensable resource, and its absence has left many ophthalmologists and retina specialists without a reliable alternative.

“The relaunch of TRIESENCE, following more than five years on the FDA Drug Shortage List and two years of inventory depletion, brings much-needed relief for both eyecare professionals and their patients. During its absence, many were forced to adapt with less ideal, off-label solutions such as modifying preserved Kenalog-40, which posed potential risks. Now that TRIESENCE is back, we can confidently provide safer, more effective treatment, improving surgical outcomes and patient care.”

Dr. John W. Kitchens, MD, an ophthalmologist and vitreoretinal surgeon with Retina Associates of Kentucky, added, “I believe every retinal specialist in the U.S. joins me in thanking Harrow for their extraordinary efforts in bringing TRIESENCE back to market. Its potent anti-inflammatory properties also play a critical role in managing severe ocular inflammatory conditions that don’t respond to topical treatments, reducing swelling, pain, and the risk of long-term damage. I couldn't be more excited to have this vital tool back in my armamentarium, ensuring the best possible care for patients.”

Billing and Ordering TRIESENCE

TRIESENCE (J3300 Injection, triamcinolone acetonide, preservative-free, 1 mg) is a single-use vial of 40 milligrams or 40 units based on the HCPCS descriptor.

Healthcare providers may order TRIESENCE directly through major pharmaceutical specialty distributors, including Besse Medical/Cencora, McKesson Medical-Surgical, and Cardinal Health. Initial supplies of TRIESENCE will be listed under both NDC 00078-0897-78 and NDC 82667-0800-01.

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 prescription and non-prescription 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 and 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 filing 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.

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

HIGHLIGHTS OF TRIESENCE PRESCRIBING INFORMATION

INDICATIONS AND USAGE

TRIESENCE suspension is a synthetic corticosteroid indicated for:

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

DOSAGE AND ADMINISTRATION

- Initial recommended dose for all indications except visualization: 4 mg (100 microliters of 40 mg/mL suspension) with subsequent dosage as needed over the course of treatment.
- Recommended dose for visualization: 1 to 4 mg (25 to 100 microliters of 40 mg/mL suspension) administered intravitreally.

DOSAGE FORMS AND STRENGTHS

Single use 1 mL vial containing 40 mg/mL of triamcinolone acetonide suspension.

CONTRAINDICATIONS

- Patients with systemic fungal infections.
- Hypersensitivity to triamcinolone or any component of this product.

WARNINGS AND PRECAUTIONS

- TRIESENCE suspension 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.

DRUG INTERACTIONS

- Anticoagulant agents: May enhance or diminish anticoagulant effects. Monitor coagulation indices.
- Antidiabetic agents: May increase blood glucose concentrations. Dose adjustments of antidiabetic agents may be required.
- CYP 3A4 inducers and inhibitors: May respectively increase or decrease clearance of corticosteroids necessitating dose adjustment.
- Non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and salicylates: Increased risk of gastrointestinal side effects.

For complete product information about TRIESENCE, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3f045347-3e5e-4bbd-90f8-6c3100985ca5.

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Investors
Jamie Webb
Director of Communications and Investor Relations
jwebb@harrowinc.com

615-733-4737

Media
Deb Holliday
Holliday Communications, Inc.
deb@hollidaycommunications.net
412-877-4519

Source: Harrow, Inc.