Harrow Completes Transfer of the TRIESENCE® New Drug Application

November 29, 2023

NASHVILLE, Tenn.--(BUSINESS WIRE)--Nov. 29, 2023-- Harrow (Nasdaq: HROW), a leading U.S. eyecare pharmaceutical company, today announced the completion of the transfer to Harrow of the New Drug Application (NDA) for TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/mL, a synthetic corticosteroid indicated for the treatment of sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids as well as visualization during vitrectomy. In January of 2023, Harrow agreed to acquire the U.S. commercial rights to TRIESENCE. Aside from the transfer of the TRIESENCE NDA ahead of the date previously agreed to, all other acquisition terms remain unchanged.

“While we continue to diligently work with our contract manufacturing partner, making solid progress manufacturing commercial batches of TRIESENCE, the mutual agreement to an early transfer of the TRIESENCE NDA was an important step in advancing our strategy to re-launch the product under the Harrow umbrella,” said Mark L. Baum, Chief Executive Officer of Harrow. “With this crucial process completed, our team has begun to implement our market access, marketing, inventory management, national sales detailing, and other brand-leveraging strategies so that we will be ready to re-launch TRIESENCE in the U.S. once we have achieved a successful inventory build, which we are currently working diligently towards. We remain excited to be able to provide TRIESENCE to the U.S. ophthalmic community soon.”

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.

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 U.S. market. Harrow helps U.S. eyecare professionals preserve the gift of sight by making its comprehensive portfolio of prescription and non-prescription pharmaceutical products accessible and affordable to millions of Americans 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, including its Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20231129601830/en/

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.