



Harrow Provides TRIESENCE® Relaunch Update

June 20, 2024

Successful Manufacture of TRIESENCE PPQ Batch Leads to Scheduling of Remaining Process Qualification Steps, Initial Inventory Build, and Pre-Commercial Activities

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jun. 20, 2024-- Harrow (Nasdaq: HROW), a leading North American eyecare pharmaceutical company, is pleased to announce the successful manufacture of the first of three commercial-scale process performance qualification (PPQ) batches of TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/mL, a preservative-free synthetic corticosteroid that is FDA-approved for visualization during vitrectomy and for the treatment of ocular inflammatory conditions that are unresponsive to topical corticosteroids. Harrow also announced that the second and third required PPQ batches are now scheduled; and should these PPQ batches meet specifications, the new TRIESENCE production process will be deemed complete, allowing Harrow to relaunch during 2024.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20240620854415/en/>



TRIESENCE (Photo: Business Wire)

TRIESENCE has been on the FDA Drug Shortage List for over five years with all TRIESENCE inventories having been depleted in the U.S. market for over two years. Harrow remains committed to making

TRIESENCE available to U.S. ophthalmologists and retina specialists.

Mark L. Baum, Chairman and Chief Executive Officer of Harrow, commented, “We are delighted to confirm the successful completion of the first of three TRIESENCE PPQ batches. This milestone resulted from the commitment of teams working in South America, Europe, and the United States to reinvent the complex manufacturing and analytical testing process for TRIESENCE. We believe this work and these results improve our prospects for successfully completing the balance of the TRIESENCE qualification process and for our ability to build commercial inventories going forward. Although our initial TRIESENCE inventory build may not fully meet the expected demands of the market, we are committed to collaborating closely with our manufacturing partner to expedite the production of additional batches as quickly as possible.

“TRIESENCE, a trusted and high-utility solution for ophthalmologists and retina specialists, has not been easily or economically replaceable during this lengthy shortage and out-of-stock period. Concurrent with our technical team completing the validation of the TRIESENCE qualification process, Harrow’s commercial leadership is initiating pre-commercialization activities, including discussions with strategic accounts to pre-order the expected initial inventory of TRIESENCE.”

If you are an ophthalmologist, retina specialist, or an institution interested in securing a quantity allocation of TRIESENCE, please complete the following [form](#) for an immediate supply review.

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, 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](https://www.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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