Harrow Completes Transfer of NDAs and Launches FLAREX®, NATACYN®, TOBRADEX® ST, VERKAZIA®, and ZERVIATE® in the U.S.

October 24, 2023

NASHVILLE, Tenn.--(BUSINESS WIRE)--Oct. 24, 2023-- Harrow (Nasdaq: HROW), a leading U.S. eyecare pharmaceutical company, today announced the completion of the transfer to Harrow of the New Drug Applications (NDAs) for the following products:

- **FLAREX®** (fluorometholone acetate ophthalmic suspension) 0.1%, a corticosteroid indicated for use in the treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye.
- **NATACYN®** (natamycin ophthalmic suspension) 5%, a sterile antifungal for treating fungal blepharitis, conjunctivitis, and keratitis caused by susceptible organisms, including Fusarium solani keratitis.
- **TOBRADEX® ST** (tobramycin and dexamethasone ophthalmic suspension) 0.3%/0.05%, an antibiotic and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.
- **VERKAZIA®** (cyclosporine ophthalmic emulsion) 0.1%, a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults and holds orphan-drug exclusivity.
- **ZERVIATE®** (cetirizine ophthalmic solution) 0.24%, a histamine-1 (H1) receptor antagonist indicated for treating ocular itching associated with allergic conjunctivitis.

Harrow announced its acquisition of the U.S. commercial rights of these products in July of 2023. To date, Harrow has been receiving profit transfers on these products; however, with the transfer of the NDAs completed, Harrow has launched these products in the U.S. under the Harrow name.

Please see select Important Safety Information for these products and links to the Full Prescribing Information at the end of this release.

In commenting on the announcement, Mark L. Baum, Chief Executive Officer of Harrow, said, “With the completion of the NDA transfer process for the branded ophthalmic portfolio that we recently acquired, our marketing and sales teams are hard at work implementing commercial strategies aimed at increasing brand awareness and sales for these products. These products and others we acquired this year support a growing awareness among U.S. eyecare professionals that Harrow is exclusively focused on and committed to serving U.S. eyecare professionals with a full range of high-quality, accessible, and affordable products they need to care for their patients.”

Product orders for FLAREX, NATACYN, TOBRADEX ST, VERKAZIA, and ZERVIATE can be made directly through Harrow’s dedicated customer service ordering partner, Cardinal’s Cordlogistics, which includes a wholesaler distribution system encompassing McKesson and AmerisourceBergen.

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 that 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 the continued impact of the COVID-19 pandemic and any future health epidemics on our financial condition, liquidity and results of operations; our ability to make commercially available our FDA-approved products and compounded formulations and technologies in a timely manner or at all; market acceptance of the Company’s products and challenges related to the marketing of the Company’s products; risks related to our pharmacy operations; our ability to enter into other strategic alliances, including arrangements with pharmacies, physicians and healthcare organizations for the development and distribution of our products; our ability to obtain intellectual property protection for our assets; our ability to accurately estimate our expenses and cash burn, and raise additional funds when necessary; risks related to research and development activities; the projected size of the potential market for our technologies and products; unexpected new data, safety and technical issues; regulatory and market developments impacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry; competition; and market conditions. 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 website 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 FLAREX® (fluorometholone acetate ophthalmic suspension) 0.1%:

INDICATIONS AND USAGE

FLAREX® (fluorometholone acetate ophthalmic suspension) 0.1% is indicated for use in the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye.

CONTRAINDICATIONS

Contraindicated in acute superficial herpes simplex keratitis, vaccinia, varicella, and most other viral diseases of cornea and conjunctiva; mycobacterial infection of the eye; fungal diseases; acute purulent untreated infections, which like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid; and in those persons who have known hypersensitivity to any component of this preparation.

SELECT WARNINGS

FOR TOPICAL OPHTHALMIC USE. NOT FOR INJECTION. Use in the treatment of herpes simplex infection requires great caution. Prolonged use may result in glaucoma, damage to the optic nerve, defect in visual acuity and visual field, cataract formation and/or may aid in the establishment of secondary ocular infections from pathogens due to suppression of host response. Acute purulent infections of the eye may be masked or exacerbated by presence of steroid medication. Topical ophthalmic corticosteroids may slow corneal wound healing. In those diseases causing thinning of the cornea or sclera, perforation has been known to occur. If these products are used for 10 days or longer, intraocular pressure (IOP) should be routinely monitored.

ADVERSE REACTIONS

Glaucoma with optic nerve damage, visual acuity and field defects, cataract formation, secondary ocular infection following suppression of host response, and perforation of the globe may occur.

For complete product information about FLAREX®, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=19918ea5-8568-44d6-b8ee-7b2197cee85c.

About NATACYN® (natamycin ophthalmic suspension) 5%:

INDICATIONS AND USAGE

NATACYN® (natamycin ophthalmic suspension) 5% is indicated for the treatment of fungal blepharitis, conjunctivitis, and keratitis caused by susceptible organisms including Fusarium solani keratitis. As in other forms of suppurative keratitis, initial and sustained therapy of fungal keratitis should be determined by the clinical diagnosis, laboratory diagnosis by smear and culture of corneal scrapings and drug response. Whenever possible the in vitro activity of natamycin against the responsible fungus should be determined. The effectiveness of natamycin as a single agent in fungal endophthalmitis has not been established.

CONTRAINDICATIONS

NATACYN® (natamycin ophthalmic suspension) 5% is contraindicated in individuals with a history of hypersensitivity to any of its components.

SELECT PRECAUTIONS

General: FOR TOPICAL OPHTHALMIC USE ONLY — NOT FOR INJECTION. Failure of improvement of keratitis following 7-10 days of administration of the drug suggests that the infection may be caused by a microorganism not susceptible to natamycin.

ADVERSE REACTIONS

The following events have been identified during post-marketing use of NATACYN ® (natamycin ophthalmic suspension) 5% in clinical practice: allergic reaction, change in vision, chest pain, corneal opacity, dyspnea, eye discomfort, eye edema, eye hyperemia, eye irritation, eye pain, foreign body sensation, paresthesia, and tearing.

For complete product information about NATACYN®, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2818fcb8-5bac-41fb-864e-3b598308a428.

About TOBRADEX® ST (tobramycin and dexamethasone ophthalmic suspension) 0.3%/0.05%:

INDICATIONS AND USAGE

TOBRADEX® ST ophthalmic suspension is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

CONTRAINDICATIONS

Nonbacterial Etiology: TOBRADEX® ST, as with other ophthalmic corticosteroids, is contraindicated in most 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.

Hypersensitivity: Hypersensitivity to a component of the medication.

SELECT WARNINGS AND PRECAUTIONS

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

Aminoglycoside Sensitivity: Sensitivity to topically applied aminoglycosides may occur.

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

Delayed Healing: The use of steroids after cataract surgery may delay healing.

Bacterial Infections: Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections.

Viral Infections: Use in patients with a history of herpes simplex requires great caution as it 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.

Vision Blurred: Vision may be temporarily blurred following dosing with TOBRADEX ST. Care should be exercised in operating machinery or driving a motor vehicle.

Risk of Contamination: Do not touch the dropper tip of the bottle to any surface, as this may contaminate the contents.

*Contact Lens Use: T*OBRADEX® ST contains benzalkonium chloride, an antimicrobial preservative, that may be absorbed by soft contact lenses. Contact lenses should not be worn during the use of TOBRADEX ST.

ADVERSE REACTIONS

Clinical Trials Experience: The most frequent adverse reactions to topical ocular tobramycin (TOBREX ®) are hypersensitivity and localized ocular toxicity, including eye pain, eyelids pruritus, eyelid edema, and conjunctival hyperemia. These reactions occur in less than 4% of patients.

For complete product information about TOBRADEX® ST, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c2d7325e-4f58-5590-e053-2a95a90ace1b.

About VERKAZIA® (cyclosporine ophthalmic emulsion) 0.1%:

INDICATIONS AND USAGE

VERKAZIA® ophthalmic emulsion is indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults.

ADVERSE REACTIONS

The most common adverse reactions reported in greater than 5% of patients were eye pain (12%) and eye pruritus (8%) which were usually transitory and occurred during instillation.

For complete product information about VERKAZIA®, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c795cd2f-89da-78e3-e053-2a95a90a9422.

About ZERVIATE® (cetirizine ophthalmic solution) 0.24%

INDICATIONS AND USAGE

ZERVIATE® (cetirizine ophthalmic solution) 0.24% is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

SELECT WARNINGS AND PRECAUTIONS

Contamination of Tip and Solution: As with any eye drop, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle or tip of the single-use container in order to avoid injury to the eye and to prevent contaminating the tip and solution. Keep the multi-dose bottle closed when not in use. Discard the single-use container after using in each eye.

Contact Lens Wear: Patients should be advised not to wear a contact lens if their eye is red.

ZERVIATE should not be instilled while wearing contact lenses.

ADVERSE REACTIONS

The most commonly reported adverse reactions occurred in approximately 1–7% of patients treated with either ZERVIATE or vehicle. These reactions were ocular hyperemia, instillation site pain, and visual acuity reduced.

For complete product information about ZERVIATE®, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3e6fecc1-df71-4c01-a654-f55635617a7f.

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