Harrow Acquires Santen's Branded Ophthalmic Portfolio

July 18, 2023

Transaction Includes U.S. and Canadian Commercial Rights to FLAREX®, NATACYN®, TOBRADEX® ST, VERKAZIA®, ZERVIATE®, and Non-Prescription Brands FRESHKOTE® and Cationorm® PLUS

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jul. 18, 2023-- Harrow (Nasdaq: HROW), a leading U.S. eyecare pharmaceutical company, today announced the signing of agreements with affiliates of Santen Pharmaceutical Co., Ltd. ("Santen") under which Harrow will acquire certain U.S. and Canadian commercial rights for the following branded products from Santen:

U.S. 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 indicated for the treatment of 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 treatment of ocular itching associated with allergic conjunctivitis.

- FRESHKOTE®, used as a lubricant to reduce further irritation or to relieve dryness of the eye.

Canadian Products:

- VERKAZIA® (cyclosporine ophthalmic emulsion) 0.1%, a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis (VKC) in children from four years of age through adolescence.
- Cationorm® PLUS, a preservative-free emulsion for the treatment of dry eye symptoms and for the treatment of signs and symptoms of ocular allergy.

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 transaction, Mark L. Baum, Chairman and Chief Executive Officer of Harrow, stated, "This acquisition furthers Harrow's goal of becoming a leader in the top tier of U.S. ophthalmic pharmaceutical companies, makes Harrow's branded portfolio one of the most comprehensive in the U.S. market, and is expected to be immediately financially accretive upon the transfer of the product marketing authorizations. We are excited to add several high utility and trusted products that serve the ophthalmic surgical market, a market in which we already have a strong presence, and significantly expand the breadth of our portfolio, which will now include the only FDA-approved ophthalmic antifungal; a patented and 'orphan-designated' product for the nearly 50,000 Americans suffering from the rare disease vernal keratoconjunctivitis (or VKC); a patented prescription drug to treat ocular itching associated with allergies; and two patented non-prescription brands serving patients managing dry eye symptoms."

Richard L. Lindstrom, M.D. added, "As an ophthalmic surgeon of nearly 50 years and an advisor to Mark and the Harrow leadership team for many years, I am pleased to see Harrow step up and assemble not only a formidable posterior segment offering with products like IHEEZO® and TRIESENCE®, but also an impressive array of innovative anterior segment products that U.S. ophthalmologists and optometrists rely on to care for their patients. While some ophthalmic pharmaceutical companies have decided to place less emphasis on the anterior segment despite the growing demand in this category of eyecare, with this acquisition, few companies, if any, can match the scope and depth of Harrow's ophthalmic product offerings, especially in the anterior segment. I believe this level of commitment to the eyecare professional should further strengthen and expand the many relationships Harrow has been able to forge over the past 10 years."

Financing for the transaction was provided through the expansion of Harrow's secured credit facility with funds managed by Oaktree Capital Management, L.P. Harrow management expects the transaction to reduce the Company's aggregate leverage ratio of adjusted EBITDA to debt.

About Harrow
Harrow Health, Inc. (Nasdaq: HROW) is a leading U.S. eyecare pharmaceutical company engaged in the discovery, development, and commercialization of innovative ophthalmic prescription therapies that are accessible and affordable. Harrow owns U.S. commercial rights to ten branded FDA-approved ophthalmic pharmaceutical products. Harrow also owns and operates ImprimisRx, a leading U.S. ophthalmic-focused

pharmaceutical compounding business, which also serves as a mail-order pharmacy licensed to ship prescription medications in all 50 states. Harrow has non-controlling equity positions in Surface Ophthalmics, Inc. and Melt Pharmaceuticals, Inc., companies that began as subsidiaries of Harrow. Harrow also owns royalty rights in four late-stage drug candidates being developed by Surface and Melt.

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; and 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 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.

Information for U.S. Products:

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: TOBRADEX® 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.

Information for Canadian Products

About VERKAZIA® (cyclosporine topical ophthalmic emulsion) 0.1% w/v

Verkazia (cyclosporine) is indicated for treatment of severe vernal keratoconjunctivitis in children from four years of age through adolescence.

For complete Canadian product information about Verkazia, including important safety information, please visit: https://pdf.hres.ca/dpd_pm/00048991.PDF.

About Cationorm® PLUS

Cationorm® PLUS is an ophthalmic sterile preservative-free eye drop emulsion used for:

treatment of dry eye symptoms: It helps to hydrate, lubricate and protect the ocular surface. It is recommended for the relief of dry eye symptoms characterized by stinging, itching or burning eyes or by a foreign body sensation (sand, dust, etc.).

treatment of signs and symptoms of ocular allergy: It is recommended for the relief of ocular allergy symptoms characterized by itching, tearing, mucous discharge and photophobia, and the protection of the ocular surface (corneal staining improvement). Cationorm® PLUS can be used in children from four years old.

Do not use Cationorm® PLUS if you are allergic to any of the components of the product. This product is not intended for treating other eye conditions. Please consult your doctor or pharmacist if you have any questions. If you currently use other eye drops, you should wait at least 5 minutes between the administrations of each successive eye drop. It is recommended to use Cationorm® PLUS last.

Cationorm® PLUS is compatible with all kinds of contact lenses.

In very rare cases, a transient ocular discomfort such as: eye irritation, eye pain, eye redness, watery eyes, eye discharge, temporarily blurred vision, eyelids inflammation, eyelids edema or transient discomfort at instillation can appear. These symptoms are also part of typical symptoms of dry eye disease linked to the underlying existing medical conditions in the patient's eyes suffering from dry eye or ocular allergy.

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