# Harrow Launches ILEVRO®, NEVANAC®, and MAXIDEX® in the U.S.

May 2, 2023

NASHVILLE, Tenn.--(BUSINESS WIRE)--May 2, 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 ILEVRO® (nepafenac ophthalmic suspension) 0.3%, NEVANAC® (nepafenac ophthalmic suspension) 0.1%, and MAXIDEX® (dexamethasone ophthalmic suspension) 0.1%. These three FDA-approved ophthalmic medicines, which are now commercially available under the Harrow umbrella, were among the five products that Harrow purchased in January of 2023 and for which Harrow has been receiving net profits from unit sales during the NDA transfer process. Harrow expects to complete the transfer of the NDAs for the two remaining products, VIGAMOX® (moxifloxacin hydrochloride ophthalmic solution) 0.5% and TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/ml, by year-end.

“We are delighted to have completed the NDA transfer process for ILEVRO, NEVANAC, and MAXIDEX earlier than our originally estimated six-month period,” said Mark L. Baum, Chief Executive Officer of Harrow. “We can now implement our market access, marketing, inventory management, and national sales detailing strategies for each of these three products, and we expect to extend those efforts when the NDAs for the remaining two products, VIGAMOX and TRIESENCE, are transferred later this year.

“Our market research has shown that the market need for all five of these products continues to increase with U.S. demographic growth and that there are few, if any, new competitive threats, particularly in the NSAID market. These products are used during procedures and within markets in which Harrow already has a strong foothold, and we look forward to making these well-known and valuable ophthalmic medicines available to the eyecare professionals that we serve nationwide as we continue to execute our branded ophthalmic pharmaceuticals market strategy.”

Product orders for ILEVRO, NEVANAC, and MAXIDEX 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 ILEVRO®** (nepafenac ophthalmic suspension) 0.3%

ILEVRO® (nepafenac ophthalmic suspension) 0.3%, a nonsteroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.

**INDICATIONS AND USAGE**

ILEVRO® 0.3% is indicated for the treatment of pain and inflammation associated with cataract surgery.

**CONTRAINDICATIONS**

ILEVRO® 0.3% is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other nonsteroidal anti-inflammatory drugs (NSAIDs).

**WARNINGS AND PRECAUTIONS**

*Increased Bleeding Time.* With some NSAIDs including ILEVRO® 0.3%, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery. It is recommended that ILEVRO® 0.3% be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

*Delayed Healing.* Topical NSAIDs including ILEVRO® 0.3%, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

*Corneal Effects.* Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration, or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including ILEVRO® 0.3% and should be closely monitored for corneal health.

Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events, which may become sight threatening. Topical NSAIDs should be used with caution in these patients. Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events.

*Contact Lens Wear.* ILEVRO® 0.3% should not be administered while using contact lenses.

**ADVERSE REACTIONS**

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be

directly compared to the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

*Serious and Otherwise Important Adverse Reactions.* The following adverse reactions are discussed in greater detail in other sections of labeling: (1) Increased Bleeding Time, (2) Delayed Healing and (3) Corneal Effects.

*Ocular Adverse Reactions.* The most frequently reported ocular adverse reactions following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation. These reactions occurred in approximately 5 to 10% of patients. Other ocular adverse reactions occurring at an incidence of approximately 1 to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing and vitreous detachment. Some of these reactions may be the consequence of the cataract surgical procedure.

*Non-Ocular Adverse Reactions.* Non-ocular adverse reactions reported at an incidence of 1 to 4% included headache, hypertension, nausea/vomiting, and sinusitis.

**About NEVANAC®** (nepafenac ophthalmic suspension) 0.1%

NEVANAC® (nepafenac ophthalmic suspension) 0.1% is a nonsteroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.

**INDICATIONS AND USAGE**

NEVANAC® 0.1% is indicated for the treatment of pain and inflammation associated with cataract surgery.

**CONTRAINDICATIONS**

NEVANAC® 0.1% is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other NSAID.

**WARNINGS AND PRECAUTIONS**

*Increased Bleeding Time.* With some NSAIDs including NEVANAC® 0.1%, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery. It is recommended that NEVANAC® 0.1% be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

*Delayed Healing.* Topical NSAIDs including NEVANAC® 0.1%, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

*Corneal Effects.* Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration, or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including NEVANAC® 0.1% and should be closely monitored for corneal health.

Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events, which may become sight threatening. Topical NSAIDs should be used with caution in these patients. Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events.

*Contact Lens Wear.* NEVANAC® 0.1% should not be administered while using contact lenses.

**ADVERSE REACTIONS**

The following adverse reactions are discussed in greater detail in other sections of labeling: (1) Increased Bleeding Time, (2) Delayed Healing and (3) Corneal Effects.

*Clinical Trial Experience.* Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

*Ocular Adverse Reactions.* The most frequently reported ocular adverse reactions following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation. These reactions occurred in approximately 5 to 10% of patients. Other ocular adverse reactions occurring at an incidence of approximately 1 to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing and vitreous detachment. Some of these reactions may be the consequence of the cataract surgical procedure. The most frequently reported ocular adverse reactions following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure (IOP), and sticky sensation. These reactions occurred in approximately 5% to 10% of patients. Other ocular adverse reactions occurring at an incidence of approximately 1% to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing, and vitreous detachment. Some of these reactions may be the consequence of the cataract surgical procedure. Non-ocular adverse reactions reported at an incidence of 1% to 4% included headache, hypertension, nausea/vomiting, and sinusitis.

**About MAXIDEX® (dexamethasone ophthalmic suspension) 0.1%**

MAXIDEX (dexamethasone ophthalmic suspension) 0.1% is an adrenocortical steroid prepared as a sterile topical ophthalmic suspension.

**INDICATIONS AND USAGE**

Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic

conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitides when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.

**CONTRAINDICATIONS**

Contraindicated in acute, untreated bacterial infections; mycobacterial ocular infections; epithelial herpes simplex (dendritic keratitis); vaccinia, varicella, and most other viral diseases of the cornea and conjunctiva; fungal disease of ocular structures; and in those persons who have shown hypersensitivity to any component of this preparation.

**WARNINGS**

Prolonged use may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions or parasitic infections of the eye, corticosteroids may mask infection or enhance existing infection. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. If these products are used for 10 days or longer, intraocular pressure (IOP) should be routinely monitored even though it may be difficult in children and uncooperative patients. Employment of corticosteroid medication in the treatment of herpes simplex other than epithelial herpes simplex keratitis, in which it is contraindicated, requires great caution; periodic slit-lamp microscopy is essential.

**PRECAUTIONS**

*General.* FOR TOPICAL OPHTHALMIC USE. The possibility of persistent fungal infections of the cornea should be considered after prolonged corticosteroid dosing.

The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

*Information for Patients.* Do not touch dropper tip to any surface, as this may contaminate the contents. The preservative in MAXIDEX (dexamethasone ophthalmic suspension) 0.1%, benzalkonium chloride, may be absorbed by soft contact lenses. MAXIDEX (dexamethasone ophthalmic suspension) 0.1% should not be administered while wearing soft contact lenses.

*Carcinogenesis, Mutagenesis, Impairment of Fertility.* Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of MAXIDEX (dexamethasone ophthalmic suspension) 0.1%.

*Pregnancy.* Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ophthalmic application in multiples of the therapeutic dose. In the mouse, corticosteroids produce fetal resorptions and a specific abnormality, cleft palate. In the rabbit, corticosteroids have produced fetal resorptions and multiple abnormalities involving the head, ears, limbs, palate, etc. MAXIDEX (dexamethasone ophthalmic suspension) 0.1% should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus. There are no adequate or well-controlled studies in pregnant women. However, prolonged or repeated corticoid use during pregnancy has been associated with an increased risk of intra-uterine growth retardation. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

*Nursing Mothers.* Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when MAXIDEX (dexamethasone ophthalmic suspension) 0.1% is administered to a nursing woman.

*Pediatric Use.* The safety and effectiveness of MAXIDEX have been established in the pediatric patients. Use of MAXIDEX in all pediatric age groups is supported by evidence from adequate and well-controlled studies of MAXIDEX in adults with safety data from additional adequate and well-controlled trials in pediatric patients.

*Geriatric Use.* No overall differences in safety or effectiveness have been observed between elderly and younger patients.

**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.

*Clinical Studies Experience.* In clinical studies with MAXIDEX, the most frequently reported adverse reactions were ocular discomfort occurring in approximately 10% of the patients and eye irritation occurring in approximately 1% of the patients. All other adverse reactions from these studies occurred with a frequency less than 1%, including keratitis, conjunctivitis, dry eye, photophobia, blurred vision, eye pruritis, foreign body sensation, increased lacrimation, abnormal ocular sensation, eyelid margin crusting, and ocular hyperemia.

*Postmarketing Experience.* Additional adverse reactions identified from post-marketing use include corneal erosion, dizziness, eye pain, eyelid ptosis, headache, hypersensitivity reactions, and mydriasis. Frequencies cannot be estimated from the available data. The following additional adverse reactions have been reported with dexamethasone use: Cushing's syndrome and adrenal suppression may occur after use of dexamethasone in excess of the listed dosing instructions in predisposed patients, including children and patients treated with CYP3A4 inhibitors.

Please see Full Prescribing Information for ILEVRO, NEVANAC, and MAXIDEX.

**About Harrow**

Harrow (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 FDA-approved ophthalmic

pharmaceutical products. Harrow also owns and operates ImprimisRx, the 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 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.

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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