Harrow Enters into Agreement to Acquire Exclusive U.S. Rights to ILEVRO®, NEVANAC®, VIGAMOX®, MAXIDEX®, and TRIESENCE®

December 14, 2022

NASHVILLE, Tenn.--(BUSINESS WIRE)--Dec. 14, 2022-- Harrow (Nasdaq: HROW), an eyecare pharmaceutical company exclusively focused on the discovery, development, and commercialization of innovative ophthalmic therapies, today announced that it has entered into a binding agreement for the acquisition of the exclusive U.S. commercial rights to five FDA-approved ophthalmic products from the Novartis group of companies ("Novartis"). This acquisition, when closed, will further expand and diversify Harrow's portfolio of branded pharmaceutical products and its ability to serve the U.S. ophthalmic surgical and acute care markets. Subject to customary closing conditions, this acquisition is expected to close in early 2023.

This transaction, which is the second acquisition transaction between Harrow and Novartis, transfers exclusive U.S. rights to the following ophthalmic products:

- ILEVRO® (nepafenac ophthalmic suspension) 0.3%, a non-steroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.
- NEVANAC® (nepafenac ophthalmic suspension) 0.1%, a non-steroidal, anti-inflammatory eye drop indicated for pain and inflammation associated with cataract surgery.
- VIGAMOX® (moxifloxacin hydrochloride ophthalmic solution) 0.5%, a fluoroquinolone antibiotic eye drop for the treatment of bacterial conjunctivitis caused by susceptible strains of organisms.
- MAXIDEX® (dexamethasone ophthalmic suspension) 0.1%, a steroid eye drop for steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.
- TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/ml, a steroid injection for the treatment of certain ophthalmic diseases and for visualization during vitrectomy.

Mark L. Baum, Chairman and CEO of Harrow, stated, "This is a landmark transaction for Harrow, catapulting Harrow into a leadership position in the U.S. ophthalmic pharmaceuticals market. Following the satisfaction of the relevant closing conditions, these products will be immediately accretive to our revenues and excellently complement our current portfolio of ophthalmic prescription products.

"We know these products very well and have long appreciated and admired them for the value they have delivered to thousands of U.S. eyecare professionals and many millions of their patients. We believe the addition of these five products to our ophthalmic pharmaceutical portfolio, which includes newly FDA-approved IHEEZO®, MAXITROL® 3.5mg/10,000 units/0.1%, IOPIDINE® 1%, and the market-leading ImprimisRx compounded formulary, will be of tremendous value to our customers – giving them more choices and flexibility when considering the best treatment options for their patients and the specific needs of their practices.

"Our market research indicates an increasing demand for the indications these products treat. Based on U.S. demographic growth, favorable competitive trends, and broad public and private payor reimbursement, revenue contribution from these products is expected to grow for many years. Assuming this transaction closes during the first quarter of 2023, Harrow expects 2023 net revenues to be between $135 million and $143 million and adjusted EBITDA to be between $44 million and $50 million, with both net revenues and adjusted EBITDA ramping up during 2024 and beyond."

Under the terms of the agreement:

- Harrow will make a one-time payment of $130 million at closing, with up to an additional $45 million payable in a milestone payment upon the commercial availability of TRIESENCE, which is expected in the second half of 2023.
- During an estimated 6-month NDA transfer period, Novartis will continue to sell the products in the U.S. market and will transfer all net profits to Harrow.
- Following the NDA transfer period, Harrow will assume control over all U.S. market activities and will begin a process to have the products manufactured by third parties.
- Novartis will retain all rights to the products outside of the U.S.
- The transaction is expected to close in the first quarter of 2023, subject to the satisfaction of customary closing conditions, including clearance under the Hart-Scott Rodino Antitrust Improvements Act.

About ILEVRO® (nepafenac ophthalmic suspension) 0.3%:

INDICATIONS AND USAGE

ILEVRO® (nepafenac ophthalmic suspension) 0.3% is a nonsteroidal, anti-inflammatory prodrug indicated for the treatment of pain

and inflammation associated with cataract surgery.

IMPORTANT SAFETY INFORMATION

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* – There exists the potential for increased bleeding time. Ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery.
- *Delayed Healing* – Use may slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- *Corneal Effects* – Use may result in keratitis. In some 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 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.
- 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

The most frequently reported ocular adverse reactions following cataract surgery occurring in approximately 5% to 10% of patients were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation.

For complete product information about ILEVRO® 0.3%, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f089b583-0310-4ca8-8d41-52b06b08d1ed.

About NEVANAC® (nepafenac ophthalmic suspension) 0.1%:

INDICATIONS AND USAGE

NEVANAC® is a nonsteroidal, anti-inflammatory prodrug indicated for the treatment of pain and inflammation associated with cataract surgery.

IMPORTANT SAFETY INFORMATION

Contraindications

Hypersensitivity to any of the ingredients in the formula or to other non-steroidal anti-inflammatory drugs (NSAIDS).

Warnings and Precautions

- *Increased Bleeding Time* – There exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery.
- *Delayed Healing* – Use may slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- *Corneal Effects* – Use 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.
- 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.
- 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

Most common adverse reactions (5% to 10%) are capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure (IOP), and sticky sensation.

For complete product information about NEVANAC®, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a2909252-c5f1-421f-9073-b7be90b45b51.

About VIGAMOX® (moxifloxacin hydrochloride ophthalmic solution) 0.5%:

INDICATIONS AND USAGE

VIGAMOX® is a topical fluoroquinolone anti-infective indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: Corynebacterium species*, Micrococcus luteus*, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri*, Streptococcus pneumoniae, Streptococcus viridans group, Acinetobacter lwoffii*, Haemophilus influenzae, Haemophilus parainfluenzae*, and Chlamydia trachomatis.

*Efficacy for this organism was studied in fewer than 10 infections.

IMPORTANT SAFETY INFORMATION

Contraindications

VIGAMOX® is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

Warnings and Precautions

- *Hypersensitivity Reactions* – Hypersensitivity and anaphylaxis have been reported with systemic use of moxifloxacin.
- *Prolonged Use* – May result in overgrowth of non-susceptible organisms, including fungi.
- *Avoid Contact Lens Wear* – Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

Adverse *Reactions*

The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1%-6% of patients.

Nonocular adverse events reported at a rate of 1%-4% were fever, increased cough, infection, otitis media, pharyngitis, rash, and rhinitis.

For complete product information about VIGAMOX®, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ad783689-2b59-448c-b0d6-e8b70cf8b062.

About MAXIDEX® (dexamethasone ophthalmic suspension) 0.1%:

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.

IMPORTANT SAFETY INFORMATION

Contraindications

MAXIDEX® 0.1% is 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 and Precautions

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.

Adverse Reactions

In clinical studies with MAXIDEX, the most frequently reports 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.

For complete product information about MAXIDEX®, including additional important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=603f0bac-16b8-42f5-985e-fb0d73ee284d.

About TRIESENCE® (triamcinolone acetonide injectable suspension) 40 mg/ml:

INDICATIONS AND USAGE

TRIESENCE® suspension is a synthetic corticosteroid indicated for treatment of sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids as well as visualization during vitrectomy.

IMPORTANT SAFETY INFORMATION

Contraindications

TRIESENCE® is contradicted in patients with systemic fungal infections or 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.

Adverse Reactions

The most common reported adverse events following administration of triamcinolone acetonide were elevated intraocular pressure and cataract progression. These events have been reported to occur in 20-60% of patients.

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 (Nasdaq: HROW) is an eyecare pharmaceutical company exclusively focused on the discovery, development, and commercialization of innovative ophthalmic prescription therapies for the U.S. market that are accessible and affordable. For more information about Harrow, please visit the Investors section of the corporate website, 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 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 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.

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