Harrow Enters into 340B Prime Vendor Program Contract with Apexus™ for IHEEZO® and Other Key Harrow Products

July 9, 2024

Contract Enhances Purchasing Power for 340B Prime Vendor Program (PVP) Participants; Aligns with Harrow's Mission to Make Its Products Accessible and Affordable

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jul. 9, 2024-- Harrow (Nasdaq: HROW), a leading North American eyecare pharmaceutical company, today announced that as of July 1, 2024, it has entered into an agreement with Apexus to make IHEEZO® (chloroprocaine hydrochloride ophthalmic gel) 3% and other Harrow products available through its 340B Prime Vendor Program. IHEEZO, indicated for ocular anesthesia, is a low-viscosity topical ocular anesthetic gel with reliable efficacy, a proven safety profile, and simple administration. Other Harrow products available through the program include VIGAMOX®, a topical eye drop for bacterial conjunctivitis, and ILEVRO®, an ocular nonsteroidal anti-inflammatory (NSAID) topical eye drop for pain and inflammation.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20240709623740/en/

In commenting on the agreement, Mark L. Baum, Chairman and Chief Executive Officer of Harrow, said, "We believe the value this agreement provides to eligible participants will open access to IHEEZO for the U.S. hospital market. According to the U.S. Centers for Disease Control and Prevention, approximately 2.4 million annual emergency room visits in U.S. hospitals are due to eye-related problems, including the removal of foreign bodies and other acute conditions, many of which require anesthetizing the eye. Consistent with our commitment to ensure access and affordability to our products, with around 44% of U.S. hospitals participating in the Apexus 340B Prime Vendor Program, we are thrilled about the potential benefits we see from our new relationship, especially for vulnerable populations."

The 340B Prime Vendor Program, managed by Apexus, is a contract awarded by the Health Resources and Services Administration ("HRSA"), an agency of the U.S. Department of Health and Human Services, which is responsible for administering the 340B Drug Pricing Program. As the Prime Vendor, Apexus contracts with manufacturers and distributors to help ensure access to discounted medications, provides 340B education to all stakeholders, and helps support program integrity through technical assistance.

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. 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 IHEEZO® (chloroprocaine hydrochloride ophthalmic gel) 3%

- IHEEZO is a sterile, single-patient-use, physician-administered, ophthalmic gel preparation, containing no preservatives, that is safe and effective for ocular surface anesthesia.
- IHEEZO was approved by the FDA on September 26, 2022.
- Clinical trials of IHEEZO demonstrated that patients treated with IHEEZO did not require any supplemental treatment to complete the intended surgical procedure.

- IHEEZO represents the first approved use in the U.S. ophthalmic market of chloroprocaine hydrochloride and the first branded ocular anesthetic approved for the U.S. ophthalmic market in nearly 14 years.
- IHEEZO is protected by an Orange Book-listed patent that is valid until 2038.

INDICATIONS AND USAGE

IHEEZO™ is indicated for ocular surface anesthesia.

CONTRAINDICATIONS

IHEEZO™ is contraindicated in patients with a history of hypersensitivity to any component of this preparation.

WARNINGS AND PRECAUTIONS

IHEEZO™ should not be injected or intraocularly administered. Patients should not touch the eye for at least 10 to 20 minutes after using an anesthetic as accidental injuries can occur due to insensitivity of the eye. Prolonged use of a topical ocular anesthetic may produce permanent corneal opacification and ulceration with accompanying visual loss. Do not touch the dropper tip to any surface as this may contaminate the gel. IHEEZO™ is indicated for administration under the direct supervision of a healthcare provider. IHEEZO™ is not intended for patient self-administration.

ADVERSE REACTIONS

The most common adverse reaction is mydriasis (approximately 25%).

For complete product information about IHEEZO®, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ea3b2d2c-8b33-d199-e053-2995a90a699c.

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 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.

For complete product information about ILEVRO®, including important safety information, please visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=10f411d3-a81e-074a-e063-6294a90ab547.

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