Harrow Health Announces Launch of IOPIDINE® 1% and MAXITROL® in the United States

June 24, 2022

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jun. 24, 2022-- Harrow Health, Inc. (NASDAQ: HROW), an ophthalmic-focused healthcare company, today announced the completion of the transfer to Harrow of the New Drug Applications (NDAs) of recently acquired, FDA-approved ophthalmic medicines, IOPIDINE® 1%, MAXITROL® 3.5mg/10,000 units/0.1%, and MOXEZA® 0.5%. Harrow also announced that IOPIDINE 1% and MAXITROL are now commercially available; Harrow intends to commercialize MOXEZA 0.5% at a later date. Harrow purchased these medicines in December 2021 and has been receiving net profits from unit sales during the NDA transfer process.

“We are pleased to have completed the transfer of the NDAs for these workhorse products, allowing us to market and sell these well-known products under the Harrow umbrella,” said Mark L. Baum, CEO of Harrow Health. “We believe there is strong interest from physicians and their patients, hospitals, and ambulatory surgery centers (ASCs) in these products. The transfer of these NDAs gives Harrow a foundation to begin market access initiatives and lead conversations with commercial payer decision makers as we continue to execute our branded ophthalmic pharmaceuticals strategy.”

Product orders for IOPIDINE 1% and MAXITROL can be made directly through Harrow’s dedicated customer service ordering partner, Cardinal’s Cordlogistics, which includes a wholesaler distribution system that encompasses McKesson and AmerisourceBergen.

About IOPIDINE® (apraclonidine hydrochloride ophthalmic solution) **1%**

IOPIDINE 1% Ophthalmic Solution contains apraclonidine hydrochloride, an alpha-adrenergic agonist, in a sterile isotonic solution for topical application to the eye.

INDICATIONS AND USAGE

IOPIDINE 1% Ophthalmic Solution is indicated to control or prevent post-surgical elevations in intraocular pressure (IOP) that occur in patients after argon laser trabeculoplasty, argon laser iridotomy, or Nd:YAG posterior capsulotomy.

CONTRAINDICATIONS

IOPIDINE 1% Ophthalmic Solution is contraindicated for patients receiving monoamine oxidase inhibitor therapy and for patients with hypersensitivity to any component of this medication or to clonidine.

WARNINGS

FOR TOPICAL OPHTHALMIC USE ONLY. Not for injection or oral ingestion.

PRECAUTIONS

General

Patients who develop exaggerated reductions in IOP should be closely monitored. Caution should be observed in treating patients with severe cardiovascular disease including hypertension. IOPIDINE 1% Ophthalmic Solution should also be used with caution in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, Raynaud’s disease, or thromboangiitis obliterans.

The possibility of a vasovagal attack occurring during laser surgery should be considered and caution used in patients with a history of such episodes.

Information for Patients

Apraclonidine can cause dizziness and somnolence. Patients who engage in hazardous activities requiring mental alertness should be warned of the potential for a decrease in mental alertness on the day of surgery.

Adverse Reactions

The following adverse events, occurring in less than 2% of patients, were reported in association with the use of IOPIDINE 1% Ophthalmic Solution in laser surgery: ocular injection, upper lid elevation, irregular heart rate, nasal decongestion, ocular inflammation, conjunctival blanching, and mydriasis.

About MAXITROL® (neomycin and polymyxin B sulfates and dexamethasone ophthalmic suspension) **3.5mg/10,000 units/0.1%**

MAXITROL® (neomycin and polymyxin B sulfates and dexamethasone ophthalmic suspension) is a multiple dose anti-infective steroid combination in sterile suspension form for topical application.

INDICATIONS AND USAGE

For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial infection exists. Ocular corticosteroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of corticosteroids use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation, or thermal burns; or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

The particular anti-infective drug in this product is active against the following common bacterial eye pathogens: Staphylococcus aureus, Escherichia coli, Haemophilus influenzae, Klebsiella/Enterobacter species, Neisseria species, and Pseudomonas aeruginosa. This product does not provide adequate coverage against: Serratia marcescens and Streptococci, including Streptococcus pneumoniae.

CONTRAINDICATIONS

MAXITROL® (neomycin and polymyxin B sulfates and dexamethasone ophthalmic suspension) is contraindicated in most viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. MAXITROL is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

WARNINGS

NOT FOR INJECTION. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended. Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections. Acute purulent or parasitic infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication.

Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation. If this product is used for 10 days or longer, intraocular pressure (IOP) should be routinely monitored even though it may be difficult in children and uncooperative patients. Steroids should be used with caution in the presence of glaucoma. IOP should be checked frequently.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

MAXITROL® is not for injection. It should never be injected subconjunctivally, nor should it be directly introduced into the anterior chamber of the eye. Products containing neomycin sulfate may cause cutaneous sensitization. Sensitivity to topically administered aminoglycosides, such as neomycin, may occur in some patients. The severity of hypersensitivity reactions may vary from local effects to generalized reactions such as erythema, itching, urticaria, skin rash, anaphylaxis, anaphylactoid reactions, or bullous reactions. If hypersensitivity develops during the use of the product, treatment should be discontinued. Cross-hypersensitivity to other aminoglycosides can occur, and the possibility that patients who become sensitized to topical neomycin may also be sensitive to other topical and/or systemic aminoglycosides should be considered.

PRECAUTIONS

General

The initial prescription and renewal of the medication order beyond 20 mL of MAXITROL® 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 two days, the patient should be reevaluated.

As fungal infections of the cornea are particularly prone to develop coincidentally with long-term corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate. Prolonged use of topical anti-bacterial agents may give rise to overgrowth of non-susceptible organisms including fungi.

Information for Patients

If inflammation or pain persists longer than 48 hours or becomes aggravated, the patient should be advised to discontinue the use of the medication and consult a physician.

This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the bottle tip to eyelids or to any other surface. The use of this bottle by more than one person may spread infection. Keep the bottle tightly closed when not in use. Keep out of reach of children.

Patients should be advised that their vision may be temporarily blurred following dosing with MAXITROL® (neomycin and polymyxin B sulfates and dexamethasone ophthalmic suspension). Care should be exercised in operating machinery or driving a motor vehicle.

Adverse Reactions

The reactions due to the corticosteroid component are: elevation of IOP with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing. Corticosteroid-containing preparations have also been reported to cause perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, and conjunctival hyperemia have occasionally been reported following use of steroids.

Additional adverse reactions identified from post marketing use include ulcerative keratitis, headache, and Stevens-Johnson syndrome.

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.

About MOXEZA® (moxifloxacin ophthalmic solution) 0.5%

MOXEZA® (moxifloxacin ophthalmic solution) is a sterile solution for topical ophthalmic use.

INDICATIONS AND USAGE

MOXEZA is a topical fluoroquinolone anti-infective indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: Aerococcus viridans*, Corynebacterium macginleyi*, Enterococcus faecalis*, Micrococcus luteus*, Staphylococcus arlettae*, Staphylococcus aureus, Staphylococcus capitis, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus saprophyticus*, Staphylococcus warneri*, Streptococcus mitis*, Streptococcus pneumoniae, Streptococcus parasanguinis*, Escherichia coli*, Haemophilus influenzae, Klebsiella pneumoniae*, Propionibacterium acnes, Chlamydia trachomatis.*

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

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Corneal Endothelial Damage and Toxic Anterior Segment Syndrome

NOT FOR INTRACAMERAL USE OR INJECTION. MOXEZA will cause damage to the corneal endothelium if introduced directly into the anterior chamber of the eye.

Toxic Anterior Segment Syndrome (TASS) has been reported following intraocular administration of moxifloxacin. TASS is typically characterized by anterior chamber inflammatory reactions, such as fibrin, cell or flare and corneal edema, but other events, such as hypopyon, keratic precipitates or vitreous opacities may also occur.

Hypersensitivity Reactions

In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

Growth of Resistant Organisms With Prolonged Use

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining.

Avoidance of Contact Lens Wear

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

Information for Patients

Avoid Contamination of the Product

Advise patients not to touch the dropper tip to any surface to avoid contaminating the contents.

Avoid Contact Lens Wear

Advise patients not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Hypersensitivity Reactions

Systemically administered quinolones, including moxifloxacin, have been associated with hypersensitivity reactions, even following a single dose. Advise patients to discontinue use immediately and contact their physician at the first sign of a rash or allergic reaction [see Warnings and Precautions].

Adverse Reactions

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

The data described below reflect exposure to MOXEZA in 1263 patients, between 4 months and 92 years of age, with signs and symptoms of bacterial

conjunctivitis. The most frequently reported adverse reactions were eye irritation, pyrexia and conjunctivitis, reported in 1% to 2% of patients.

Please see Full Prescribing Information for IOPIDINE, MAXITROL, and MOXEZA.

About Harrow Health

Harrow Health, Inc. (NASDAQ: HROW) is an ophthalmic-focused healthcare company. The Company owns and operates ImprimisRx, one of the nation's leading ophthalmology-focused pharmaceutical businesses, and Visionology, a direct-to-consumer eye care subsidiary focused on chronic vision care. Harrow Health also holds non-controlling equity positions in Eton Pharmaceuticals, Surface Ophthalmics and Melt Pharmaceuticals, all of which started as Harrow Health subsidiaries, and owns royalty rights in four clinical-stage drug candidates being developed by Surface Ophthalmics and Melt Pharmaceuticals. For more information about Harrow Health, please visit the Investors section of the corporate website, harrowinc.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 Health'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 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 Health 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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