Harrow Announces Transitional Pass-Through Reimbursement Status for IHEEZO™ (Chloroprocaine Hydrochloride Ophthalmic Gel) 3%

March 13, 2023

NASHVILLE, Tenn.--(BUSINESS WIRE)--Mar. 13, 2023-- Harrow (Nasdaq: HROW), a leading U.S. eyecare pharmaceutical company, today announced that the Centers for Medicare & Medicaid Services (CMS) has approved transitional pass-through reimbursement status for IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3%, which is indicated for ocular surface anesthesia.

Beginning April 1, 2023, and for the three years thereafter, IHEEZO will be eligible for separate reimbursement outside of the surgical bundled payment in both the Ambulatory Surgery Center (ASC) and Hospital Outpatient Department (HOPD) settings of care. CMS previously approved the issuance of a permanent, product-specific J-Code (J2403), enabling access to IHEEZO for ophthalmologists, optometrists, and retina specialists for the in-office setting of care. This new CMS pass-through approval makes IHEEZO the only ocular anesthetic with separate reimbursement in all traditional settings of care – the eyecare professional's office, the ASC, and the HOPD.

CMS grants pass-through status to certain new and innovative medical devices, drugs, and biological products. Drugs that are administered in the ASC and HOPD settings can have pass-through status and be reimbursed accordingly by Medicare. By having pass-through status, IHEEZO will be separately reimbursed by Medicare at Average Sales Price (ASP) +6% in both the ASC and HOPD settings of care. Until an ASP is established, IHEEZO will be reimbursed accordingly at Wholesale Acquisition Cost (WAC) +3%.

"We are grateful to CMS for their approval of transitional pass-through reimbursement status for IHEEZO and for their support of our mission to make innovative ophthalmic prescription medications accessible and affordable," said Mark L. Baum, Chairman and Chief Executive Officer of Harrow. "With approximately 5 million cataract surgeries and more than 8 million intravitreal injections performed each year in the U.S., we believe that IHEEZO's receipt of both a permanent J-Code, which we announced on February 2, 2023, and now, pass-through reimbursement status, will contribute to greater patient access to this important new treatment to anesthetize the eye. We remain on track for the commercial launch of IHEEZO at the May 2023 American Society of Cataract and Refractive Surgery (ASCRS) meeting in San Diego."

About IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3%

- IHEEZO is a sterile, single-patient-use, physician-administered, ophthalmic gel preparation, containing no preservatives, for ocular surface anesthesia.
- IHEEZO was approved by the FDA on September 26, 2022.
- In a clinical trial of IHEEZO in patients undergoing routine cataract surgery, patients treated with IHEEZO did not require any supplemental treatment to complete the intended surgical procedure.
- IHEEZO represents the first branded ocular surface anesthetic approved for the U.S. 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 additional information about IHEEZO™, including important safety information, please see the *Full Prescribing Information* on the www.IHEEZO.com website.

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 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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