Harrow Announces U.S. FDA Approval of IHEEZO™ (Chloroprocaine Hydrochloride Ophthalmic Gel) 3% for Ocular Surface Anesthesia

September 27, 2022

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™ was Licensed by Harrow for the U.S. and Canadian Markets From 100-Year-Old International Pharmaceutical Company Sintetica, S.A.

NASHVILLE, Tenn. & MENDRISIO, Switzerland--(BUSINESS WIRE)--Sep. 27, 2022-- Harrow (Nasdaq: HROW), an eyecare pharmaceutical company exclusively focused on the discovery, development, and commercialization of innovative ophthalmic therapies, and Sintetica, S.A., a growing pharmaceutical company focused on analgesics, local anesthetics, and sterile injectable solutions, today jointly announced the U.S. Food and Drug Administration (FDA) approval of IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3% for ocular surface anesthesia. 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 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.

“On behalf of all our ophthalmic physician partners and the patients they serve, we and our partners at Sintetica are grateful to the FDA for a New Drug Application (NDA) review process that resulted in the approval of IHEEZO in advance of our PDUFA target action date,” said Mark L. Baum, Harrow Chairman and Chief Executive Officer. “We have always believed in the unique clinical value of IHEEZO, and now that IHEEZO is approved for use in the U.S. market, it has the potential to become an indispensable premium tool for eyecare professionals and their patients requiring ocular surface anesthesia.”

Nicola Caronzolo, Sintetica Chief Executive Officer, added, “I am particularly proud of this important milestone, which exemplifies the quality of Sintetica’s research and development groups and our ability to innovate – to be a global pharmaceuticals leader. I want to give special thanks to our regulatory group, who while working with the Harrow team, performed extraordinarily well, resulting in this early U.S. market approval for this important new medicine.”

The safety and efficacy of IHEEZO were demonstrated in three human clinical studies. Studies 1 and 2 were randomized, double-blinded, placebo-controlled studies that evaluated the effect of IHEEZO on healthy volunteers, and Study 3 was a randomized, prospective, multi-center, active-controlled, observer-masked study that evaluated the administration of IHEEZO in patients undergoing cataract surgery. Study 3 marks the first time a U.S. drug candidate was studied in a surgical model for FDA approval in the ocular surface anesthesia category. This study demonstrated that IHEEZO not only worked rapidly (about 1 to 1.5 minutes) and provided sufficient anesthesia to successfully perform the surgical procedure (on average lasting 22 minutes), but importantly, no patient dosed with IHEEZO required a supplemental treatment to complete the surgical procedure.

According to a September 2021 report by *Market Scope*, there are an estimated 4.5 million cataract surgeries and over 8 million intravitreal injections performed annually in the U.S., all of which typically utilize some form of ocular surface anesthesia.

Baum continued, “Harrow currently provides perioperative medications for a significant number of the U.S. ophthalmic surgical procedures. We believe our customer base of more than 10,000 ophthalmologists, optometrists, retina specialists, outpatient hospital facilities, and ambulatory surgery centers will appreciate the unique clinical value and practice efficiency IHEEZO offers, including its single-use packaging format, which according to the Institute for Safe Medication Practices (ISMP), decreases the risk of infection and medication errors associated with the use of communal eye drops.

“We have been planning for the commercial launch of IHEEZO for over a year, and with our national market access and sales organization already in place, we are 100% ready. Given our earlier FDA approval date, we have accelerated our market access strategy to support a commercial launch date slightly ahead of our previously planned launch at the May 2023 American Society of Cataract and Refractive Surgery (ASCRS) meeting in San Diego, CA.”

About IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3%

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.

About Harrow

Harrow (Nasdaq: HROW) is an eyecare pharmaceutical company exclusively focused on the discovery, development, and commercialization of innovative ophthalmic therapies that are accessible and affordable. For more information about Harrow, including investment-related materials, please visit the corporate website, harrowinc.com, or Harrow's LinkedIn page.

About Sintetica

Based in Mendrisio, Switzerland, Sintetica is a growing privately held international pharmaceutical company focused on emergency and intensive care, analgesics, local anesthetics and sterile injectable solutions in ampoules, vials and IV bags for hospitals. Sintetica develops medicines in concentrated, premixed and ready-to-use formulations, which enables healthcare practitioners to administer these products without manipulation and dilution, increasing patient safety and improving convenience for patients and HCPs. Sintetica runs sales subsidiaries in selected European markets and partners with leading distributors around the world.

Harrow 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 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 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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