Harrow Announces Availability of VEVYE® (Cyclosporine Ophthalmic Solution) 0.1%, the First and Only Cyclosporine-Based Product Indicated for Treating Both Signs and Symptoms of Dry Eye Disease

January 11, 2024

VEVYE® Offers Rapid Onset with Clinically and Statistically Meaningful Improvement

Beginning as Early as 15 Days[1] with Sustained Improvement over 56 Weeks[2]

VEVYE® Patients to Have Access to a 100% Money-Back Guarantee Program[3]

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jan. 11, 2024-- Harrow (Nasdaq: HROW), a leading U.S. eyecare pharmaceutical company, today announced that VEVYE® (cyclosporine ophthalmic solution) 0.1%, a patented, non-preserved, twice-daily (BID) dosed prescription drug based on a "water -free" semifluorinated alkane eyedrop technology, is **now available in the U.S.** *– and includes a 100% Money-Back Guarantee program*. VEVYE, uniquely dispensed in a 10 microliter drop, is the first and only cyclosporine-based product indicated for treating both the signs and symptoms of dry eye disease (DED).

In commenting on the announcement, Mark L. Baum, Chairman and Chief Executive Officer of Harrow, said, "We are thrilled to announce the availability of VEVYE for our customers and their patients. VEVYE is powered by the unique combination of the reliable and trusted active ingredient, cyclosporine, and a water-free semifluorinated alkane delivery vehicle, perfluorobutylpentane. We are excited to see VEVYE's exceptional clinical trial data come to life as U.S. dry eye disease patients are now able to access and experience a highly tolerable product that provides rapid onset of relief and sustained improvement of both signs and symptoms of dry eye disease. Because of VEVYE's unique combination of both a potent 0.1% cyclosporine solute and a pH- and osmolarity-free semifluorinated alkane, VEVYE is both evolutionary and revolutionary, solving an unmet need for eyecare professionals treating the tens of millions of American chronic dry eye disease sufferers."

Dry eye disease (DED) is a common condition that occurs when the eyes do not produce enough tears or when the tears evaporate too quickly, and it is often associated with chronic inflammation. Untreated DED can lead to discomfort such as stinging, burning or blurry vision, and chronic DED can interfere with daily activities like reading and using a computer. More serious consequences include increased risk of eye infections and damage to the surface of the eye, which can potentially result in serious vision problems and even loss of sight. Causes of dry eye are varied and can include aging, certain medications, medical conditions, or environmental factors such as increased screen time and exposure to pollutants, all of which are contributing to a forecast of continued significant increase in DED. According to a 2020 report from *Market Scope*, DED affects more than 38 million Americans. In addition, 92% of this patient population remains un- or under-treated due to limited efficacy and poor tolerability of existing prescription and non-prescription choices.[4]

Comments from Ophthalmic KOLs (Key Opinion Leaders) on VEVYE

"As an ophthalmologist and ocular surface specialist, I have served as principal investigator in over 120 clinical trials, half of which targeted dry eye disease. As participants in VEVYE's clinical trials, our team found the results to be compelling. The data in both consecutive registration trials demonstrated impressive efficacy, safety and tolerability, with rapid clinical onset beginning as early as 15 days and continuous improvement for more than one year. VEVYE represents not just an innovative treatment; it exemplifies the penultimate synthesis of outstanding vehicle with cyclosporine, the active pharmaceutical ingredient, boasting a superlative decades long track record. Tolerability and risk profile are impressive compared with most existing dry eye products, portending improved patient compliance. Indicated for both signs and symptoms, VEVYE should expand the market and fundamentally enhance dry eye disease treatment algorithms."

—John D. Sheppard, M.D., M.M.Sc., F.A.C.S., corneal external disease fellowship trained ophthalmologist and founding senior partner of Virginia Eye Consultants, Norfolk, VA

"When a patient presents with dry eye disease, it is often difficult to initially classify them into a specific category, such as aqueous deficient, evaporative, or a combination of the two. In addition, they often present with inflammation leading to many of their dry eye symptoms. That is why VEVYE, with cyclosporine in a semifluorinated alkane solution, provides us with a valuable tool to address the signs and symptoms of dry eye holistically, regardless of etiology."

—Paul Karpecki, OD, FAAO, Director, cornea and external disease, Kentucky Eye Institute, and associate professor, Kentucky College of Optometry UPIKE, Lexington, KY

"VEVYE continues the trend of advanced cyclosporine formulations coming to market that are designed to address key issues of onset of action and tolerability. As the first cyclosporine with an FDA indication for signs and symptoms and the first anti-inflammatory drop in the new category of anhydrous or water-free formulations, VEVYE is well-positioned to add unique clinical value to the expanding market of excellent anti-inflammatory dry eye disease therapeutics."

—Richard Adler, M.D., corneal, refractive, and external disease fellowship trained ophthalmologist at Belcara Health, Baltimore, MD

“As a glaucoma specialist who treats advanced glaucoma, I’ve been looking forward to the availability of VEVYE, a two-hit treatment for ocular surface disease targeting longstanding inflammation and corneal damage in as quickly as 15 days. A large portion of patients with glaucoma also have dry eye disease with extensive cornea damage due to the use of topical glaucoma medications. I look forward to the rapid relief my patients will receive from the addition of preservative-free VEVYE.”

—Courtney Bovee, M.D., cataract and glaucoma surgeon at The Macula Center and Blue Ocean Clinical Research Center, Tampa Bay, FL.

“Clinicians have been waiting a long time for a dry eye treatment that combines the effectiveness of cyclosporine with the tolerability of this unique semifluorinated alkane vehicle. In VEVYE, the vehicle makes all the difference, allowing the product to spread evenly over the ocular surface with longer residual time and increased penetration of cyclosporine.”

—John A. Hovanesian, M.D., cataract, corneal and laser eye surgeon and a principal at Harvard Eye Associates, Laguna Hills, CA

“As an eyecare professional, I recognize the critical need for a dry eye product that not only acts swiftly and effectively, but also is comfortable enough to encourage continued patient use. A dry eye product that is well tolerated, has no or mild discomfort or adverse effects, and can easily be incorporated into a patient’s daily routine is key to successful long-term management of dry eye syndrome. VEVYE’s twice -daily dosing should also contribute to patient compliance, thus promoting overall effectiveness of the treatment. I am excited to see the positive changes that VEVYE can bring to patients suffering from dry eye disease.”

—William B. Trattler, M.D., cataract, refractive, and corneal surgeon and Director of Cornea at the Center for Excellence in Eye Care, Miami, FL

How to Order VEVYE

Eyecare professionals can send prescriptions for VEVYE, using their electronic medical record (EMR), directly to Harrow’s dedicated pharmacy partner, PhilRx. Prescriptions can also be sent to any retail pharmacy. VEVYE is fully stocked in the wholesale distribution channel and can be shipped to any retail pharmacy, generally within 24 hours of order placement.

In addition, VEVYE is available directly through the wholesale distributors, including McKesson, Cardinal and Cencora (f/k/a AmerisourceBergen).

Interested patients should ask their trusted eyecare professional whether VEVYE is right for them.

VEVYE Patient Access Program

Harrow has established a VEVYE Patient Access program, under which eligible patients may receive their first VEVYE prescription for as low as $0.[5]

Harrow also offers a 100% money-back guarantee for eligible patients.[3]

More information on Harrow’s Patient Access program is available at getvevye.com.

For more information about VEVYE, please visit vevye.com.

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 U.S. market. Harrow helps U.S. eyecare professionals preserve the gift of sight by making its comprehensive portfolio of prescription and non-prescription pharmaceutical products accessible and affordable to millions of Americans 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 VEVYE® (cyclosporine ophthalmic solution) 0.1%

VEVYE (cyclosporine ophthalmic solution) 0.1%, non-preserved, for topical ophthalmic use. Approved by the U.S. Food and Drug Administration (FDA) in June 2023, VEVYE combines a semifluorinated alkane eyedrop technology (perfluorobutylpentane) with cyclosporine 0.1% in solution. VEVYE is indicated to treat both the signs and symptoms of DED. Clinical trials for VEVYE have demonstrated that it not only increases tear production, but it also has been shown to improve the cornea surface as evidenced by total corneal fluorescein staining (tCFS). Clinical trials also show that VEVYE’s clinical benefits begin as early as 15 days and show sustained improvement over 12 months – all while maintaining an excellent patient tolerability and low adverse event profile.

INDICATIONS AND USAGE

VEVYE is indicated for the treatment of the signs and symptoms of dry eye disease.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Potential for Eye Injury and Contamination. To avoid the potential for eye injury and/or contamination, patients should not touch the bottle tip to the eye or other surfaces.

Use with Contact Lenses. VEVYE should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to administration of the solution. Lenses may be reinserted 15 minutes following administration of VEVYE ophthalmic solution.

ADVERSE REACTIONS

Clinical Trials Experience. 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 rates in the clinical trials of another drug and may not reflect the rates observed in practice. In clinical trials with 738 subjects receiving at least 1 dose of VEVYE, the most common adverse reactions were instillation site reactions (8%) and temporary decreases in visual acuity (3%).

USE IN SPECIAL POPULATIONS

Pregnancy. There are no adequate and well-controlled studies of VEVYE administration in pregnant women to inform a drug-associated risk.

Lactation. Caution should be exercised when VEVYE is administered to a nursing woman.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For additional information about VEVYE, please see the Full Prescribing Information.

[1] Pooled study data.

[2] An open-label, single-arm, extension study.

[3] This offer is available on one fill only, and is valid only for eligible patients paying cash who do not have commercial or government insurance. This offer is not valid for patients with government insurance, including, but not limited to, Medicaid or Medicare. Contact Harrow at 833-442-7769 for information on how to apply for your money-back guarantee. Additional terms and conditions apply. This offer is available through any participating retail pharmacy.

[4] Source: Ophthalmology Innovation Source (OIS) Dry Eye Conference (March 2021)

[5] By participating in the program, patients acknowledge that they currently meet the eligibility criteria. This program is only available for eligible commercially insured patients who are dispensed VEVYE by PhilRx or another participating pharmacy. This offer is not valid for patients with government insurance, including, but not limited to, Medicaid or Medicare. A patient's out -of-pocket cost may be greater based on patient's plan benefit design. Additional terms and conditions apply. All patients, including uninsured, commercially insured, and government-insured, may be eligible for manufacturer cash discount pricing subject to program terms and conditions for opt out.

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