Harrow Announces 52-Week Data from VEVYE® ESSENCE-2 Open-Label Extension Study

June 5, 2024

Data Demonstrates Sustained Safety and Efficacy in Treating Signs and Symptoms of Dry Eye Disease

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jun. 5, 2024-- Harrow (Nasdaq: HROW), a leading North American eyecare pharmaceutical company, is pleased to announce results from its ESSENCE-2 open-label extension (OLE) clinical study for VEVYE® (cyclosporine ophthalmic solution) 0.1%, the first and only cyclosporine to treat the signs and symptoms of dry eye disease (DED). ESSENCE-2 OLE was a Phase 3, prospective, multicenter, open-label, clinical study with 202 patients, who had previously completed the ESSENCE-2 study, receiving VEVYE in each eye twice a day for 52 weeks. The one-year study results, published in *Cornea*, demonstrated VEVYE's sustained safety and efficacy in treating the signs and symptoms of DED, underscoring its value in managing this chronic condition. Key findings include:

- Statistically significant improvements in all prespecified efficacy endpoints compared with baseline at each visit.
- Corneal staining improvements were early and stabilized over time while tear production improved continuously and symptomatology improvement followed these effects.
- The most common ocular treatment-related adverse events were mild instillation site pain in 13 patients (6.5%) and reduced visual acuity in 6 patients (3.0%). One patient withdrew during the 52-week study due to an ocular adverse event (mild burning/stinging).
- On a 0 to 10 scale (the higher the number equating to a better rating), when patients were asked to rate the question, "How satisfied are you with the study eye drop?"— 33.1% of patients provided the highest possible rating of 10. Approximately 91% of patients rated a score of 5 or higher, indicating satisfaction with the treatment.
- Investigators conclude that water-free cyclosporine 0.1% ophthalmic solution was safe and well tolerated during long-term use.

Dr. John D. Sheppard, Ophthalmologist, President of Virginia Eye Consultants, and one of the investigators on the ESSENCE-2 OLE study, stated, "Topical cyclosporine has established a remarkable decades-long efficacy and safety profile. Finally, we have the right vehicle."

Dr. Laura M. Periman, Ophthalmologist and Director of Dry Eye Services and Clinical Research at Periman Eye Institute, added, "We know that tolerability is a major issue with long-term immunomodulatory medications leading to poor patient compliance and dropout. In this 52-week study, perhaps the most impressive data point was that only one patient stopped using VEVYE because of an ocular adverse event, which was mild burning and stinging. Also, patients randomized to VEVYE in ESSENCE-2 that continued into the OLE, on average, saw their natural tear production nearly double after 56 weeks of treatment from baseline. Furthermore, these patients saw a statistically significant improvement in all measured symptoms at all measured time points compared to baseline. ESSENCE-2 OLE data demonstrates the long-term potential of VEVYE for patients suffering from chronic dry eye disease."

Mark L. Baum, Chairman and Chief Executive Officer of Harrow, said, "The OLE data affirms why VEVYE is such a special product and why so many patients are now entering their sixth refill cycle. VEVYE's unique value is enabled because of its patented water-free formulation, which catalyzes additional product features and related clinical benefits[1]: *VEVYE is preservative-free, has no pH or osmolarity, and requires only twice-daily dosing with an individual dosage that is 1/10th the size of conventional eye drops*. In addition, in a pre-clinical ex-vivo corneal penetration study[2], VEVYE's semi-fluorinated alkane vehicle, *perfluorobutylpentane (PFBP)*, delivered approximately 22 times more cyclosporine into the cornea compared to RESTASIS®. This OLE data supports our efforts to make sure eyecare professionals and their patients are aware of how VEVYE helps manage dry eye disease by improving – over the longer term – the signs and symptoms of this chronic disease."

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 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 website 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.

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[1] VEVYE (cyclosporine ophthalmic solution) 0.1% (package insert). Harrow IP, LLC: 2023.

[2] Data on file. RESTASIS is not a Harrow-owned brand, and the RESTASIS trademark is the property of its respective owner.

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