Harrow Acquires U.S. and Canadian Commercial Rights to VEVYE® (Cyclosporine Ophthalmic Solution) 0.1% from Novaliq

VEVYE® is the First and Only Cyclosporine-Based Product Indicated for the Treatment of Both Signs and Symptoms of Dry Eye Disease with Efficacy Demonstrated After Four Weeks

VEVYE® is the Only Water-Free Ophthalmic Product with Convenient Twice-Daily (BID) Dosing

NASHVILLE, Tenn. & HEIDELBERG, Germany, July 18, 2023 – Harrow (Nasdaq: HROW), a leading U.S. eyecare pharmaceutical company, and Novaliq GmbH, a German biopharmaceutical company focusing on first- and best-in-class ocular therapeutics, today announced an agreement under which Harrow will acquire the U.S. and Canadian commercial rights for VEVYE® (cyclosporine ophthalmic solution) 0.1%, a patented, non-preserved, ophthalmic solution prescription drug based on Novaliq's proprietary EyeSol® water-free technology. VEVYE, which is dispensed topically in a unique 10 microliter per one drop and is labeled for twice-daily (BID) dosing, is the first and only cyclosporine-based product indicated for the treatment of both signs and symptoms of dry eye disease (DED). VEVYE was approved on May 30, 2023, by the U.S. Food and Drug Administration (FDA).

In commenting on the transaction, Mark L. Baum, Chairman and Chief Executive Officer of Harrow, said, "The acquisition of the U.S. and Canadian commercial rights to VEVYE demonstrates our commitment to the highly underserved dry eye and ocular surface inflammation markets. We are particularly excited about adding VEVYE to our portfolio because of our strong belief that the U.S. DED market is in need of a cyclosporine-based product that is generally well tolerated, improves both the signs and symptoms of DED and, critically, reduces the time it takes for patients to experience relief from this all-too-common and, in many cases, debilitating disease. VEVYE not only feels better in the eye, but it performs differently, and we believe it addresses the numerous unmet needs in the large and growing U.S. DED market. We look forward to making VEVYE available in the U.S. later this year."

"There's good news for dry eye patients and for our colleagues," commented Laura M. Periman, M.D., Director of Dry Eye Services and Clinical Research, Periman Eye Institute, in Seattle, Washington. "VEVYE, which is expected to be available soon, is a unique cyclosporine formulation indicated for treatment of the signs and symptoms of DED. The rapid onset and magnitude of improvements on ocular surface epithelial damage, combined with the tolerability of the non-aqueous vehicle, are key differentiators to existing cyclosporin formulations. These features represent an exciting advancement in addressing the medical needs of dry eye patients and clinicians."

"For patients with chronic and symptomatic dry eye disease, the tolerability profile of the medication can be critical for compliance and treatment success," said Paul Karpecki, O.D., director, Cornea and External Disease, Kentucky Eye Institute, and associate professor, University of Pikeville, Kentucky College of Optometry. "Most patients are not comfortable with drops in their eyes that cause burning or stinging. As a water-free drug product, VEVYE does not require potentially irritating ingredients, such as preservatives, oils or surfactants, and has demonstrated in clinical trials a high patient satisfaction rate. Having a new treatment option with a favorable comfort and tolerability profile is a significant advancement for the dry eye patient, especially those who experience burning and stinging with topical eye medications."

Christian Roesky, Ph.D., Chief Executive Officer of Novaliq, stated, "We are excited to partner with Harrow, one of the fastest growing and most dynamic ophthalmic pharmaceutical companies in the U.S., to commercialize VEVYE in the U.S. and Canadian markets. Harrow and its commercial team have a distinguished track record for successfully commercializing new and clinically important pharmaceutical products in the U.S. market, and they specifically have many years of experience successfully marketing cyclosporine-based formulations to U.S. eyecare professionals. The Novaliq team looks forward to supporting Harrow during the launch of VEVYE, a

truly unique and powerful new treatment option for U.S. eyecare professionals and the more than 16 million Americans who have been diagnosed with DED."

VEVYE Clinical Data

The safety and efficacy of VEVYE (development name: CyclASol®) for the treatment of dry eye disease were assessed in a total of 1,369 patients with dry eye disease, of which 738 received VEVYE.

Study CYS-001 (NCT02113293) was the first-in-human study and was conducted to investigate the safety, tolerability, and pharmacokinetics (PK) in healthy volunteers. In this study, VEVYE was shown to be safe, and no systemic exposure of cyclosporin was observed after ocular administration.

Study CYS-002 (NCT02617667, Wirta et al 2019) demonstrated that VEVYE-dosed patients showed a statistically significant early and clinically meaningful increase in Schirmer's tear test score at Day 29 compared to vehicle. Additionally, VEVYE showed greater improvement in corneal and conjunctival staining compared to (i) vehicle and (ii) Restasis® over the four-month treatment period. The favorable safety and tolerability profile of VEVYE was confirmed.

Study CYS-003 (ESSENCE-1; NCT03292809, Sheppard et al 2021) confirmed the effects seen in CYS-002. Compared to vehicle at the end of treatment, there was a statistically significant higher percentage of patients with increases of ≥10 mm from baseline in Schirmer's tear test score at Day 85. Notably, the study demonstrated statistically significant reduction in total, central corneal fluorescein and conjunctival staining scores favoring VEVYE at all time points, in addition to VEVYE meeting the primary endpoint of the study. 52.9% of patients responded within four weeks with a clinically meaningful improvement of ≥3 grades in total corneal staining, which was significantly higher compared to vehicle. Responders showed statistically significant improvements in a variety of symptoms compared to non-responders. VEVYE was safe, well tolerated, and comfortable over the three-month treatment duration.

Study CYS-004 (ESSENCE-2; NCT04523129, Akpek et al 2023) was designed to replicate CYS-003 and met the primary corneal staining endpoint. In this study, 71.6% of patients responded within four weeks with a clinically meaningful improvement of ≥3 grades in total corneal staining. Again, responders showed statistically significant improvements in a variety of symptoms compared to non-responders at Day 29. Subjects with high central corneal staining at baseline were shown to benefit from VEVYE with statistically significant improvements in their blurred vision score compared to vehicle CYS-004 studies as shown in CYS-003. Schirmer's tear test responses of ≥10 mm increase was statistically significantly higher in the VEVYE compared vehicle at Day 29. VEVYE was safe, well tolerated, and comfortable over the one-month duration.

Study CYS-005 (NCT04523142, Wirta et al 2023) was an open label extension study of CYS-004. VEVYE was shown to be safe and well tolerated during long-term use over 12 months. Sign and symptom endpoints continued to improve over the course of the study demonstrating sustained efficacy over 52 weeks of therapy in both signs and symptoms.

1. Wirta DL, Torkildsen GL, Moreira HR, Lonsdale JD, Ciolino JB, Jentsch G, Beckert M, Ousler GM, Steven P, Krösser S. A Clinical Phase II Study to Assess Efficacy, Safety, and Tolerability of Waterfree Cyclosporine Formulation for Treatment of Dry Eye Disease. Ophthalmology. 2019; 126:793-800
2. Sheppard JD, Wirta DL, McLaurin E, Boehmer BE, Ciolino CB, Meides AS, Schlüter T, Ousler GW, Usner D, Krösser S. A Water-free 0.1% Cyclosporine A Solution for Treatment of Dry Eye Disease: Results of the Randomized Phase II/III ESSENCE Study. Cornea. 2021; 40:1290-1297
3. Akpek EK, Wirta DL, Downing JE, Tauber J, Sheppard JD, Ciolino JB, Meides AS, Krösser S: Efficacy and Safety of a Water-Free Topical Cyclosporine, 0.1%, Solution for the Treatment of Moderate to Severe Dry Eye Disease: The ESSENCE-2 Randomized Clinical Trial. JAMA Ophthalmology. 2023; 141(5):459-466.
4. Wirta DL, Krösser S, Long -Term Safety and Efficacy of a Water-Free Cyclosporine Ophthalmic Solution for the Treatment of Dry-Eye Disease: ESSENCE-2-OLE study. ASCRS 2023 paper presentation.

About VEVYE® (cyclosporine ophthalmic solution) 0.1%

VEVYE (cyclosporine ophthalmic solution) 0.1%, non-preserved, for topical ophthalmic use.

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.

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

About Novaliq
Novaliq is a private biopharmaceutical company focusing on the development and commercialization of first- and best-in-class ocular therapeutics based on EyeSol®, the worldwide first water-free technology. Novaliq GmbH is headquartered in Heidelberg, Germany, and Novaliq Inc. has an office in Cambridge, MA, USA. The long-term shareholder is dievini Hopp BioTech holding GmbH & Co. KG, an active investor in Life and Health Sciences companies. More on novaliq.com.

About Harrow
Harrow Health, Inc. (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 branded FDA-approved ophthalmic pharmaceutical products. Harrow also owns and operates ImprimisRx, a 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.

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, 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; and 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 ("SEC"), 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.

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