Harrow to Initiate Phase 3 Clinical Trial Seeking to Expand TRIESENCE® Label to Include Ocular Inflammation and Pain Following Cataract Surgery Indication

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NASHVILLE, Tenn., March 03, 2026 (GLOBE NEWSWIRE) -- Harrow (Nasdaq: HROW), a leading provider of ophthalmic disease management solutions in North America, today announced that the U.S. Food and Drug Administration (FDA) has cleared an Investigational New Drug (IND) application to support a planned Phase 3 clinical trial evaluating TRIESENCE (preservative-free triamcinolone acetonide injectable suspension) 40 mg/mL for the treatment of ocular inflammation and pain following cataract surgery.

The planned Phase 3 study is a randomized, placebo-controlled, double-masked, multicenter clinical trial designed to evaluate the safety and efficacy of TRIESENCE in patients undergoing cataract surgery. Harrow expects to initiate the study in the first quarter of 2026.

Cataract surgery is among the most commonly performed surgical procedures in the United States, with more than 4 million procedures completed annually and volumes expected to grow as the population ages[i]. As procedure volumes continue to rise, solutions that improve efficiency, enhance patient experience, and reduce post-operative burden are becoming increasingly important to both surgeons and healthcare systems. Recent third-party market research further underscores this shift in surgical practice patterns. In a Market Scope survey of U.S. cataract surgeons, nearly nine out of ten respondents indicated interest in a dropless surgical approach, with roughly half characterizing themselves as highly interested[ii]. The same survey also reported meaningful patient preference for eliminating post-operative drops. Together, these findings underscore growing alignment between surgeon and patient demand for simplified perioperative care.

TRIESENCE is an FDA-approved triamcinolone preservative-free formulation for intraocular use and is widely utilized by ophthalmologists for the treatment of ocular inflammation. Adoption has been particularly strong among surgeons treating cataract patients, for whom post-operative eye drop adherence can be challenging due to dexterity hurdles, cognitive limitations, compliance concerns, limited caregiver support, or other age-related comorbidities. By expanding on-label TRIESENCE usage to all cataract surgery patients, Harrow will increase the number of patients benefiting from a preservative-free, sustained anti-inflammatory therapy at the time of surgery, reducing reliance on patients self-administering complex, multi-week at-home eye drop regimens—and addressing a well-recognized compliance challenge in post-cataract surgery care while providing physicians with greater control over post-operative inflammation management.

Harrow believes the planned Phase 3 trial represents an important opportunity to further strengthen the clinical and commercial profile of TRIESENCE. The study is designed to generate robust data supporting its use in managing post-operative inflammation and pain following cataract surgery, with the potential to expand the product's label. If successful, the trial could reinforce its current role as a differentiated and clinically meaningful option for both physicians and patients. In addition, these data would further support Harrow's long-term vision of delivering solutions that streamline surgical workflows, reduce reliance on opioids and IV sedation, and simplify post-operative care. TRIESENCE is central to this strategy and reinforces Harrow's commitment to advancing a more efficient, patient-focused cataract surgery paradigm.

"This study marks an important milestone for TRIESENCE and for Harrow," said Amir Shojaei, Chief Scientific Officer of Harrow. "TRIESENCE is already making a meaningful difference for patients with ocular inflammation by delivering sustained anti-inflammatory control at the time of surgery. Its clinical profile provides significant benefits, including effective management of post-operative inflammation and pain while enabling physicians to maintain greater control over both the procedure and the recovery process. By reducing reliance on complex at-home eye drop regimens—where compliance can be inconsistent, particularly among older patients—TRIESENCE addresses a well-recognized challenge in post cataract removal care. We believe this Phase 3 study will generate high-quality data to further support its clinical value, expand its potential role in post-cataract surgery treatment, and strengthen its long-term commercial opportunity."

The Phase 3 trial is expected to enroll approximately 250 patients who will be randomized in a 2:1 ratio to receive either TRIESENCE or placebo. The primary efficacy endpoints are the absence of anterior chamber cells in the study eye at Day 14 and the absence of pain in the study eye at Day 8 following cataract surgery. Each patient will participate in the study for approximately 120 days, with the final visit occurring on Day 90.

About the Planned Phase 3 Study:

- **Design**: Randomized, placebo-controlled, double-masked, multicenter clinical study
- **Indication**: Treatment of ocular inflammation and pain following cataract surgery

- **Planned Enrollment**: Approximately 250 patients
- **Randomization**: 2:1 (TRIESENCE: placebo)
- **Primary Endpoints**:
  - Absence of anterior chamber cells in the study eye (Day 14)
  - Absence of pain in the study eye (Day 8)
- **Study Duration**: 120 days per patient; last visit on Day 90
- **Study Initiation**: First quarter of 2026
- **Enrollment Start**: Second quarter of 2026

About Harrow

Harrow, Inc. (Nasdaq: HROW) is a leading provider of ophthalmic disease management solutions in North America, offering a comprehensive portfolio of products that address conditions affecting both the front and back of the eye, such as dry eye disease, wet (or neovascular) age-related macular degeneration, cataracts, refractive errors, glaucoma and a range of other ocular surface conditions and retina diseases. Harrow was founded with a commitment to deliver safe, effective, accessible, and affordable medications that enhance patient compliance and improve clinical outcomes. For more information about Harrow, please visit harrow.com and connect with us on LinkedIn.

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, including the ongoing communications with the U.S. Food and Drug Administration relating to compliance and quality plans at our outsourcing facility in New Jersey; 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 for the year ended December 31, 2025, and other filings with the SEC. 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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[i] Market Scope, 2024 United States Cataract Atlas
[ii] Market Scope, Ophthalmic Market Perspectives, Volume 30, Issue 2, February 24, 2026