Sight Sciences Announces Completion of Enrollment in SAHARA, a Randomized Clinical Trial of the TearCare® System vs Restasis®

September 13, 2022

- 310-patient RCT designed to evaluate the superiority of TearCare® (device) vs Restasis® (drug) in patients with chronic dry eye disease is now fully enrolled
- 6-Month efficacy results expected by Summer 2023

MENLO PARK, Calif., Sept. 13, 2022 (GLOBE NEWSWIRE) -- Sight Sciences, Inc. (Nasdaq: SGHT), an eyecare technology company focused on creating innovative solutions intended to transform care and improve patients' lives, today announced the completion of enrollment in the SAHARA Trial, a first of its kind outcomes study designed to evaluate whether an interventional dry eye procedure with the TearCare System is superior in alleviating the signs and symptoms of dry eye disease compared to 6-months of twice daily Restasis® dry eye eyedrops (cyclosporine ophthalmic emulsion, 0.05%). Primary endpoints measured by a masked assessor at 6 months include changes from baseline of Tear Breakup Time (sign) and Ocular Surface Disease Index Score (symptom). Results from the 310-patient, 1:1 randomized SAHARA trial are expected to be available in late Q2 2023.

"While topical prescription therapies play an important role in the treatment of dry eye disease, we believe the interventional TearCare procedure may be a more effective treatment for this chronic disease, based on its fast onset of action, consistent improvements in dry eye signs and symptoms, and durability of treatment effect that we have seen through other TearCare trials and regular clinical use. We are looking forward to comparing the TearCare procedure to daily cyclosporine use in all of these clinically important ways through this RCT," said Brandon Ayres, M.D., FAAO, Co-Director Cornea Fellowship Program, Wills Eye Hospital. "We look forward to the 6-month results of this landmark "device vs drug" trial for patients suffering from dry eye disease and think it could have major implications in how we think about and treat dry eye disease going forward."

SAHARA is the first multicenter, randomized controlled trial designed to evaluate whether treatment with a dry eye therapeutic device (TearCare) demonstrates superiority when randomized against a standard of care dry eye prescription topical medication (Restasis®). Patients in the TearCare group underwent an in-office eyelid debridement, 15-minute bilateral, precision controlled thermal session with TearCare, immediately followed by physician guided manual expression of the meibomian glands. Patients in the Restasis® control group self-administered 1 drop of Restasis twice a day every day for 6 months with clinical assessments completed at the 6-month timepoint. The primary superiority endpoint measures to be evaluated at six-months, a period that provides sufficient time for the complete onset of cyclosporine's mechanism of action, are mean change from baseline in tear breakup time (TBUT) and ocular surface disease index (OSDI) scores. SAHARA's two primary endpoint outcome measurements of TBUT (sign) and OSDI (symptom) are established ways in which clinicians assess dry eye disease. Following the 6-month read-out, all Restasis patients will be crossed over to the TearCare group and receive a TearCare procedure. All 310 patients will be followed for an additional 18 months to assess durability of TearCare treatment and re-treatment effect over a total clinical trial period of two years.

"We'd like to thank our clinical investigators, their site staffs, and all study subjects for their participation in our pivotal "drug vs device" dry eye trial," said Paul Badawi, Co-Founder and CEO of Sight Sciences. "We embarked on SAHARA, the largest randomized controlled trial with the longest follow-up analysis of any dry eye disease RCT, with patients and payors in mind. We've remained steadfast in our commitment to delivering best-in-category clinical outcomes and seeking comprehensive coverage and reimbursed access to TearCare for patients whose eye care practitioners believe it is a medically necessary and reasonable treatment option to address their MGD. Having consulted from the very beginning with national and regional payors to get their input on the type of trial design that would support coverage and payment for TearCare, we arrived at SAHARA. We look forward to the important results of this pivotal "drug vs device" RCT for patients suffering from chronic dry eye disease."

Additional information on the SAHARA trial can be found at www.clinicaltrials.gov.

About Sight Sciences
Sight Sciences is an eyecare technology company focused on developing and commercializing innovative solutions intended to transform care and improve patients' lives. Using minimally invasive or non-invasive approaches to target the underlying causes of the world's most prevalent eye diseases, Sight Sciences seeks to create more effective treatment paradigms that enhance patient care and supplant conventional outdated approaches. The Company's OMNI ® Surgical System is a minimally invasive glaucoma surgery (MIGS) device indicated to reduce intraocular pressure in adult patients with primary open-angle glaucoma (POAG), the world's leading cause of irreversible blindness. The Company's TearCare® System is 510(k) cleared for the application of localized heat therapy in adult patients with evaporative dry eye disease due to meibomian gland dysfunction (MGD), enabling office-based clearance of gland obstructions by an eye care professional to address the leading cause of dry eye disease. For more information, visit www.sightsciences.com.

About the TearCare® System
The TearCare System is FDA cleared and indicated for the application of localized heat therapy in adult patients with evaporative dry eye disease due to meibomian gland dysfunction, when used in conjunction with manual expression of the meibomian glands.

The TearCare System is the only device designed to evacuate obstructed meibomian glands while harnessing a natural blink experience. The system is comprised of single-use, universally fitting SmartLids™ which are placed on the eyelids to safely and effectively deliver "intelligent therapeutic heat".

The portable SmartHub™ communicates directly with the SmartLids to precisely control the amount of phase transition heating and the duration of treatment. After 15 minutes of therapeutic heat, the Clearance Assistant forceps allows the ECP to control expression of the stagnant, obstructed meibum expertly and precisely by targeting individual meibomian glands while obtaining full visual confirmation of the success of this personalized treatment.

Forward-Looking Statements

This press release, together with other statements and information publicly disseminated by the Company, contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The Company intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and includes this statement for purposes of complying with these safe harbor provisions. Any statements made in this press release or during the earnings call that are not statements of historical fact, including statements about our beliefs and expectations, are forward-looking statements and should be evaluated as such. Forward-looking statements include information concerning possible or assumed future results of operations, including descriptions of our business plan and strategies. These statements often include words such as "anticipate," "expect," "suggests," "plan," "believe," "intend," "estimates," "targets," "projects," "should," "could," "would," "may," "will," "forecast" and other similar expressions. We base these forward-looking statements on our current expectations, plans and assumptions that we have made in light of our experience in the industry, as well as our perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances at such time. Although we believe that these forward-looking statements are based on reasonable assumptions at the time they are made, you should be aware that many factors could affect our business, results of operations and financial condition and could cause actual results to differ materially from those expressed in the forward-looking statements. These statements are not guarantees of future performance or results. The forward-looking statements are subject to and involve risks, uncertainties and assumptions, and you should not place undue reliance on these forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following: estimates of our total addressable market, future revenue, expenses, capital requirements, and our needs for additional financing; our ability to enter into and compete in new markets; execution of our market strategies; the impact of the COVID-19 pandemic on our business, our customers' and suppliers' businesses and the general economy; our ability to compete effectively with existing competitors and new market entrants; our ability to scale our infrastructure; our ability to manage and grow our business by expanding our sales to existing customers or introducing our products to new customers; our ability to establish and maintain intellectual property protection for our products or avoid claims of infringement; potential effects of extensive government regulation; our abilities to obtain and maintain regulatory approvals and clearances for our products that support our revenue projections, business strategies and growth; our ability to successfully execute our clinical trial roadmap; our ability to obtain and maintain sufficient reimbursement for our products; our abilities to protect and scale our intellectual property portfolio; our ability to hire and retain key personnel; our ability to obtain financing in future offerings; the volatility of the trading price of our common stock; our expectation regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act (the "JOBS Act"); our ability to maintain proper and effective internal controls; and the other important factors discussed under the caption "Risk Factors" in our filings with the U.S. Securities and Exchange Commission, as may be updated from time to time in subsequent filings. These cautionary statements should not be construed by you to be exhaustive and are made only as of the date of this press release. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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