



## **Sight Sciences Announces the Publication of Twelve-Month Results of the SAHARA RCT Demonstrating Improved Signs and Symptoms of Dry Eye Disease for TearCare Patients Crossed Over from Restasis**

May 28, 2024

**Patients treated with a single interventional eyelid procedure enabled by TearCare® technology after receiving Restasis® for the first six months of the trial realized clinically meaningful improvements in the signs and symptoms of dry eye disease through month twelve.**

MENLO PARK, Calif., May 28, 2024 (GLOBE NEWSWIRE) -- [Sight Sciences](#), Inc. (Nasdaq: SGHT) ("Sight Sciences," or the "Company"), an eyecare technology company focused on developing and commercializing innovative, interventional technologies intended to transform care and improve patients' lives, today announced the publication of the twelve-month results from the SAHARA trial.

Patients previously treated with Restasis® (cyclosporine ophthalmic emulsion 0.05%) prescription eyedrops ("Restasis") had additional clinically meaningful improvements in the signs and symptoms of dry eye disease ("DED") when crossed over to [TearCare](#). These improvements persisted for six months through month twelve without continued Restasis use.

"Phase 2 of the RCT again demonstrates the clinical effectiveness of TearCare. It also shows that effectiveness appears to be the same whether or not a patient has had prior treatment with Restasis, demonstrating that similar results could be expected when TearCare is used as a primary or secondary treatment for DED," said Paul Badawi, Co-Founder and Chief Executive Officer of Sight Sciences.

Phase 1 of the SAHARA RCT included 345 subjects at 19 sites in 11 states randomized 1:1 to either TearCare or Restasis<sup>1</sup>. In Phase 2 of the SAHARA RCT, 163 patients who had been randomized and treated with Restasis during phase 1 were crossed over to TearCare at the six-month visit and followed for six months through Month 12 of the study.

Data from the first six months of the SAHARA RCT demonstrated that TearCare, an interventional eyelid procedure for DED, was superior at all measured time points to twice daily use of Restasis for the improvement of tear break up time ("TBUT"), the trial's primary dry eye signs endpoint and a key measure of tear stability<sup>1</sup>. TearCare was superior to Restasis in multiple other objective measures of dry eye, and demonstrated clinically meaningful improvements in several symptoms that matched or surpassed Restasis at all measured time points.

The aim of phase 2, undertaken in months six through twelve, was to demonstrate that cessation of Restasis followed by a single TearCare procedure would result in improved signs and symptoms for patients beyond what was achieved with six months of Restasis.

"These data demonstrate superior results with a dry eye treatment technology that is not reliant on patient adherence and supports the case for prioritizing interventional eye lid treatment over a prescription-based approach," said Brandon Ayres, MD, Co-Director of the Cornea Fellowship Program at Wills Eye Hospital and a Principal Investigator for the SAHARA RCT.

### **SAHARA RCT Twelve-Month Phase 2 Results:**

- The study reports TBUT improved by 1.1 seconds three months after cross-over to TearCare and improvement persisted (0.6 seconds) at month twelve, six months later. Both timepoints were statistically significantly better than the cross-over baseline ( $p < .001$ ).
- Ocular Surface Disease Index ("OSDI") had small, non-statistically significant decreases at three and six months after cessation of Restasis and a single TearCare treatment. In contrast, Symptoms Assessment in Dry Eye ("SANDE") scores showed statistically significant improvement after the cross over to TearCare. Eye Dryness Scores ("EDS") also showed improvement after cross-over at month 9 ( $p = .003$ ), however, did not reach statistical significance at month 12.
- Statistically significant improvements in all other measures of signs following cross-over to TearCare were observed at month nine and month twelve (three and six months after TearCare treatment), except for STS (not measured at month nine), which was numerically better by an average 1.0 second, but not statistically better ( $p = 0.08$ ).
- Mean OSDI, SANDE, and EDS for the cross-over patients closely matched the means observed at month six for the TearCare treatment group.
- TBUT, meibomian gland secretion score ("MGSS"), meibomian glands yielding clear liquid score ("MGYCS"), corneal and conjunctival staining scores, and STS all improved and closely approximated the six-month TearCare values from phase 1. Meibomian glands yielding any liquid score ("MGYLS") showed improvement ( $p < .001$  vs. month six) but was intermediate between the six months values for Restasis and TearCare.

**Table 1. Ocular signs outcomes.**

Ocular Symptom Parameters, mean (SD)	Study Baseline N=346	Month 6 Cross-over Visit N=326	pa (vs. BL)	Month 9	pa (vs. M6)	Month 12	pa (vs. M6)
TBUT (sec)	4.36 (1.2)	5.6 (2.6)	<.001	6.6 (3.2)	<.001	6.1 (2.8)	<.001
MGSS	7.1 (3.2)	13.3 (8.2)	<.001	17.4 (8.8)	<.001	16.1 (9.0)	<.001
No. of MGYLS (n)	1.2 (1.4)	4.1 (4.0)	<.001	5.8 (4.7)	<.001	5.6 (4.8)	<.001
No. of MGYCS (n)	0.08 (0.38)	0.76 (1.99)	<.001	1.3 (2.7)	<.001	1.0 (2.4)	.044
Corneal staining score	2.9 (2.7)	2.0 (2.4)	<.001	1.5 (1.9)	.004	1.6 (2.2)	.002
Conjunctival staining score	3.6 (3.5)	2.8 (3.2)	<.001	2.0 (2.5)	.001	1.9 (2.8)	<.001
STS (mm)	9.3 (3.1)	11.0 (6.3)	ns, .075	nm	-	12.0 (7.2)	ns, .080 <sup>b</sup>

<sup>a</sup> Mann-Whitney rank sum test. <sup>b</sup> P<.001 vs Study baseline.

Month 9 and 12 visits are 3 and 6 months post-cross-over from CsA to TC. OD and OS measurements pooled.

**Abbreviations:** BL, baseline; M6, month 6; SD, standard deviation; TBUT, tear break-up time; MGSS, meibomian gland secretion score; MGYLS, meibomian glands yielding any liquid score; MGYCS, meibomian glands yielding clear liquid score; STS, Schirmer tear score; ns, not statistically significant; nm, not measured.

Table 1 shows the observed mean values for signs at the end of phase 2 of the study for the Restasis cross-over cohort.

As the SAHARA RCT continues into Phase 3, it will provide long-term 2-year data for the durability and procedural treatment effect of TearCare.

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Paper Reference: Ayers BD, Bloomenstien MR, Loh J, Chester T, Saenz B, Echegoyen J, Kannarr SR, Rodriguez TC, Dickerson JE Jr. Improved signs and symptoms of dry eye disease for Restasis<sup>®</sup> patients following a single TearCare<sup>®</sup> treatment: phase 2 of the SAHARA study. *Clin Ophthalmol.* 2024;18:1525-1534. doi: 10.2147/OPHTH.S464379

## About Sight Sciences

Sight Sciences is an eyecare technology company focused on developing and commercializing innovative and interventional 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<sup>®</sup> Surgical System is an implant-free glaucoma surgery technology (i) indicated in the United States to reduce intraocular pressure in adult patients with primary open-angle glaucoma; and (ii) CE Marked for the catheterization and transluminal viscodilation of Schlemm's canal and cutting of the trabecular meshwork to reduce intraocular pressure in adult patients with open-angle glaucoma. Glaucoma is the world's leading cause of irreversible blindness. The Company's TearCare System technology is 510(k) cleared in the United States for the application of localized heat therapy in adult patients with evaporative dry eye disease due to meibomian gland dysfunction ("MGD") when used in conjunction with manual expression of the meibomian glands, enabling clearance of gland obstructions by physicians to address the leading cause of dry eye disease. The Company's SION<sup>®</sup> Surgical Instrument is a manually operated device used in ophthalmic surgical procedures to excise trabecular meshwork. For more information, visit [www.sightsciences.com](http://www.sightsciences.com).

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## 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 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 potential expected TearCare efficacy when it is used as a primary or secondary treatment for DED; the case for prioritizing interventional treatment over a prescription-based approach; and conduct of the next phase of the SAHARA trial. 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 forward-looking statements are subject to and involve numerous risks, uncertainties and assumptions, including those 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, and you should not place undue reliance on these statements. These cautionary statements 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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1. Ayres BD et al. A Randomized, Controlled Trial Comparing Tearcare® and Cyclosporine Ophthalmic Emulsion for the Treatment of Dry Eye Disease (SAHARA). *Clinical Ophthalmology* (2023) Volume 17 Pages 3925-3940.