Sight Sciences Receives FDA 510(k) Clearance of the TearCare® System for Treatment of Meibomian Gland Dysfunction (MGD), the Leading Cause of Dry Eye Disease

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Label expansion for evaporative dry eye due to MGD will support further efforts to drive patient access to insurance-covered TearCare treatments

MENLO PARK, Calif., Dec. 22, 2021 (GLOBE NEWSWIRE) -- Sight Sciences, Inc. (Nasdaq: SGHT), an eyecare technology company focused on creating innovative solutions intended to transform standards of care and improve patients' lives, today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of the TearCare® System for the treatment of meibomian gland dysfunction (MGD), the leading cause of dry eye disease (DED). The indication clears TearCare for the application of localized heat therapy in adult patients with evaporative DED due to MGD, when used in conjunction with manual expression of the meibomian glands.

Present in the vast majority of DED cases, MGD is largely undertreated, with no insured treatment options currently available that can address MGD as the root cause of dry eye. Meibum, a clear, oily secretion that is expressed through the eye's meibomian glands, works to coat the outermost layer of the eye and protect tears from premature evaporation. In MGD, there is abnormal thickening or hardening of meibum, and the opening of meibomian glands can become blocked, preventing meibum from reaching the tear. If left untreated, MGD can present serious consequences, including ocular surface damage, changes in tear film stability, inflammation, pain, chronic dry eye, and other symptoms that can greatly impair a person's daily life and vision. The eye care community is increasingly acknowledging the importance of treating underlying meibomian gland obstruction when present for optimal treatment of DED associated with MGD.

The TearCare System provides safe and effective localized heat therapy, in conjunction with manual gland expression, intended to help soften or liquify thickened meibum for effective gland clearance. The TearCare System's intelligent design delivers a consistent, requisite level of therapeutic heat (45 degrees Celsius) to the outer surface of the eyelids to achieve and maintain an inner eyelid temperature of 41-42 degrees Celsius — the inner eyelid temperature necessary to melt meibum. Research on the optimal melting temperature of hardened meibum suggests that precise heat delivery within this tight therapeutic temperature window is critical to achieving procedural safety and efficacy.[1] Efficacy lacks under 40 degrees Celsius at the inner eyelid, and heat exceeding 45 degrees Celsius at the outer eyelid can begin to present safety risks to patients.

The FDA clearance is based on data from multiple studies of the TearCare System, including recent safety and effectiveness clinical data from the pivotal OLYMPIA study published in *Cornea*. At one month post treatment in the OLYMPIA study, patients who received a single TearCare procedure showed significant improvements ($P < 0.0001$) in mean tear film breakup time and meibomian gland secretion score, which increased by 3.0 ± 4.4 seconds and 11.2 ± 11.1, respectively. TearCare subjects also showed significant reductions in mean eye dryness, Symptom Assessment in Dry Eye (SANDE), and Ocular Surface Disease Index (OSDI) scores ($P < 0.0001$) by 35.4 ± 34.1, 38.2 ± 31.0, and 27.9 ± 20.5, respectively. In the study, 72% of TearCare patients showed OSDI improvement by at least one severity category, and 81% of TearCare patients met Miller's definition of clinically meaningful improvement in OSDI.

"With such a significant number of DED cases caused by MGD, clinicians need a safe and effective modality to treat underlying meibomian gland obstruction in these patients," said Preeya K. Gupta, MD, Managing Director of Triangle Eye Consultants and lead author of the OLYMPIA study. "While historic treatments for dry eye, such as artificial tears and prescription eye drops, help address symptoms of dry eye and other potential causes, treatments for MGD remain an essential therapy for our dry eye patients. The OLYMPIA study further validates the safety and efficacy of the TearCare System to treat MGD, and we are excited to offer our patients an FDA-cleared option that can help clinicians clear gland obstructions and deliver better outcomes for adult MGD patients."

Sight Sciences plans to continue research efforts to help support future indications for the TearCare System and to provide additional randomized, controlled clinical data, which the company believes could help support insurance coverage for the procedure in the future.

"The entire Sight Sciences community is committed to advancing treatment for MGD patients and expanding much needed patient access to insured treatment," said Paul Badawi, Co-Founder and CEO, Sight Sciences. "MGD is the leading cause of DED and can present serious complications for patients if left untreated, yet both the understanding and treatment of MGD as the underlying cause of dry eye is still evolving. We remain dedicated to bringing an insurance recognized treatment option to the millions of underserved patients living with MGD."

The TearCare System consists of a reusable hardware controller, the SmartHub™, and a software-controlled eyelid technology called the SmartLids®. The SmartLids are applied adhesively and noninvasively to the outer surface of the eyelids and provide a universal and comfortable fit to deliver therapeutic heat within a tight therapeutic temperature window to the inner eyelid. The SmartHub system provides sensor-driven feedback to manage consistent heat of the SmartLids, and is designed to be portable and work into any office patient flow. The TearCare System leverages an open-eye design that allows patients to blink naturally throughout the procedure.

About Sight Sciences

Founded in 2011, Sight Sciences develops and commercializes intelligently designed and engineered products that target the underlying causes of the world's most prevalent eye diseases. The company currently markets two products, the OMNI ® Surgical System and the TearCare® System. For more information, visit www.sightsciences.com.

About the TearCare® System

The TearCare® System is 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.

TearCare® is a registered trademark of Sight Sciences.

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; 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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[1]Borchman D. The optimum temperature for the heat therapy for meibomian gland dysfunction. The Ocular Surface. 2019 Apr;17(2):360-364.