Sight Sciences Announces the Acceptance for Publication of GEMINI 2, a Three Year, Prospective, Multicenter Trial Demonstrating Sustained, Significant IOP and Medication Reductions Enabled with the OMNI® Surgical System Technology

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Prospective, long-term trial results are consistent with the significant body of published clinical evidence demonstrating the durable safety and effectiveness of procedures enabled with the OMNI Surgical System technology

MENLO PARK, Calif., Dec. 08, 2023 (GLOBE NEWSWIRE) -- Sight Sciences, Inc. (Nasdaq: SGHT) ("Sight Sciences"), an eyecare technology company focused on developing and commercializing innovative technology intended to transform care and improve patients' lives, today announced the acceptance for publication in Clinical Ophthalmology of the prospective, multi-center, three-year GEMINI 2 trial with long-term clinical outcomes for patients treated with the OMNI® Surgical System technology ("OMNI"). Publication is currently expected by December 31, 2023.

GEMINI 2, a prospective, multi-center, medication washout trial designed to obtain 36-month follow-up for patients treated in the original 12-month GEMINI trial, has been completed. Favorable results demonstrate sustained and clinically significant intraocular pressure ("IOP") reduction of greater than 20% and clinically significant IOP lowering medication reduction at 36 months. The prospective 3-year clinical outcomes in the GEMINI 2 trial confirm and extend the previously published 12-month data from the original GEMINI trial. GEMINI 2 included 66 patients across eleven participating sites, and all patients underwent medication wash-out at the two-year and three-year endpoints so that the IOP-lowering effect of the OMNI procedure could be better isolated and assessed.

The GEMINI study was the first prospective, multi-center clinical trial to assess the safety and effectiveness of OMNI procedures used in combination with cataract surgery in patients with mild to moderate primary open-angle glaucoma ("POAG"). GEMINI was designed to have eligibility criteria and pre-planned endpoints similar to the pivotal Micro Invasive Glaucoma Surgery ("MIGS") trabecular bypass stent trials for Hydrus ® Microstent and iStent inject® following ANSI Z80.27 guidelines including medication washout pre-surgically and at the endpoint. GEMINI was statistically powered and had *a priori* hypotheses of superiority compared to the historical control group (cataract surgery only) derived from the two stent studies.

In the original GEMINI study, at 12 months, OMNI plus cataract surgery achieved a mean IOP reduction of 8.2 mmHg (-34%). A post-hoc analysis of diurnal IOP fluctuations at one year in the GEMINI study showed that after surgery with OMNI, IOP fluctuations were significantly reduced compared to pre-surgical measurements.

GEMINI 2 Clinical Outcomes:

- Through three years, data from the GEMINI trial and GEMINI 2 study extension reported a 20% or more reduction of IOP in patients on the same or reduced medication at 24 months (mean of 27% IOP reduction) and at 36 months (mean of 29% IOP reduction).
- Sustained medication reductions at 24 and 36 months were also reported, with 77% of study patients medication-free at two years and 74% of study patients medication-free at three years post-procedure.
- The published 36-month long-term follow-up data from the GEMINI 2 multi-center trial, along with the published 2-year long-term follow-up data from the ROMEO 2 multi-center study, demonstrate that the beneficial reductions in IOP and medication use observed at the 12-month timepoint with the OMNI procedure were sustained for two and three years post-operatively.
- The low rate (1.5% over three years) of secondary surgical interventions observed over the study period suggests that patients treated with the OMNI procedure are unlikely to require more aggressive and invasive glaucoma surgery for a meaningful period of time.

GEMINI 2 Data for OMNI*	Mean IOP (mmHg)	Percent Mean IOP Reduction	Number of Medications	Percent Patients Medication Free at Each Reported Interval
Baseline	23.1		1.63	5%
12 Months	15.6	-32%	0.30	80%
24 Months	16.7	-27%	0.41	77%
36 Months	16.3	-29%	0.30	74%

*Data listed in the table is for the 66 patients at 11 investigational sites participating in GEMINI 2

Dr. Steve Sarkisian, a GEMINI 2 Investigator and a recognized glaucoma expert on MIGS, stated that “the consistency of the results observed across all published OMNI studies is striking and consistent with the clinical outcomes I have seen in my surgical glaucoma practice. The IOP effectiveness and medication reductions observed in this study are highly consistent with the existing and robust body of evidence of this technology. As a surgeon, consistent, reliable effectiveness across a broad patient population and an excellent safety profile are very important to me in offering a surgical procedure to my patients.”

“OMNI provides surgeons with access to the entire, 360-degree diseased trabeculocanalicular outflow pathway through a single clear corneal incision, with the aim of addressing all sources of outflow resistance residing in the trabecular meshwork, Schlemm’s canal, and the distal collector channels. The totality of the results from multiple peer-reviewed, published studies demonstrates that the OMNI aqueous outflow restoration procedure is safe and effective, as it delivers clinically meaningful and durable reductions in both intraocular pressure and medication use at both two and three years. This longer-term, prospective, multi-center trial data further supports the need for continued access to OMNI technology,” said Paul Badawi, co-founder and CEO of Sight Sciences.

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Paper Reference: Greenwood MD *et al*. 36-Month Outcomes from the Prospective GEMINI Study: Canaloplasty and Trabeculotomy Combined with Cataract Surgery for Patients with Primary Open-Angle Glaucoma. *Clinical Ophthalmology*.

About Sight Sciences
Sight Sciences is an eyecare technology company focused on developing and commercializing innovative solutions 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 MIGS technology 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 technology 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”) when used in conjunction with manual expression of the meibomian glands, enabling office-based clearance of gland obstructions by physicians to address the leading cause of dry eye disease. The Company’s SION™ Surgical Instrument is a manually operated device used in ophthalmic surgical procedures to excise trabecular meshwork.

For more information, visit www.sightsciences.com.

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, which statements are subject to considerable risks and uncertainties. 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 herein include, without limitation, statements concerning anticipated timing for publication of GEMINI 2 results and the continued need for access to the OMNI technology. 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 management believes these forward-looking statements are based upon reasonable assumptions at the time they are made, management cannot guarantee their accuracy or completeness. Forward-looking statements are subject to and involve risks, uncertainties and assumptions that may cause the Company’s actual results, performance or achievements to be materially different from any future results, performance, or achievements predicted, assumed or implied by such forward-looking statements. Some of the risks and uncertainties that may cause actual results to materially differ from those expressed or implied by these forward-looking statements are discussed under the caption “Risk Factors” in the Company’s filings with the SEC, 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. Sight Sciences undertakes 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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