Sight Sciences Announces Real-World 36-Month Study Confirming Long-Term Effectiveness of Standalone OMNI Surgical System in Managing Primary Open-Angle Glaucoma

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The study is the largest to date evaluating clinical outcomes of standalone canaloplasty and trabeculotomy. It analyzes real-world data from the American Academy of Ophthalmology IRIS® Registry and demonstrates sustained intraocular pressure reductions and decreased medication dependence

MENLO PARK, Calif., Jan. 07, 2025 (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 a landmark 36-month analysis evaluating the long-term effectiveness of the OMNI® Surgical System ("OMNI") in managing primary open-angle glaucoma ("POAG"). This study, in press in the *American Journal of Ophthalmology* and based on data from the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight), presents compelling evidence supporting the sustained benefits of standalone canaloplasty and trabeculotomy with OMNI, independent of cataract surgery.

This real-world study, led by Nathan M. Radcliffe, MD, of Mount Sinai School of Medicine in New York City, evaluated 230 eyes of 196 patients with POAG through up to 36 months. The results demonstrate clinically and statistically significant reductions in intraocular pressure ("IOP") through up to 36 months postoperatively, with mean reductions ranging from 5.6 to 7.1 mmHg. The study also reports a statistically significant decrease in medication use through 18 months. Eyes with lower baseline IOP experienced medication reduction through 36 months.

"There is a growing interest in using minimally invasive glaucoma surgery ("MIGS") as a standalone procedure for patients with pseudophakic or precataractous eyes," said Nathan M. Radcliffe, MD, lead investigator of the study and Associate Professor at the Mt. Sinai School of Medicine in New York. "This analysis represents one of the most comprehensive, real-world evaluations of standalone canaloplasty and trabeculotomy in these patient populations to date. Our findings underscore the ability of OMNI to achieve significant and sustained reductions in IOP and medication use over three years, reinforcing its position as a highly effective interventional treatment for patients with primary open-angle glaucoma."

Key Study Findings:

- **Sustained IOP Reduction:** Mean (SD) baseline IOP was 22.1 (6.4) mmHg. Over 36 months of follow-up, mean IOP ranged from 15.1 to 16.7 mmHg ($p<0.0001$ at every time point compared to baseline), with average eye-level reductions of 5.6 to 7.1 mmHg.
- **Greater IOP Reductions in High Baseline IOP Patients:** Subgroup analysis showed even greater IOP reductions (up to 8.9 mmHg) in patients with baseline IOP greater than 18 mmHg. Eyes with lower baseline IOP (<18 mmHg) had reductions in medication use through 36 months, and eyes with higher baseline IOP (>18 mmHg) had statistically significant reductions in IOP and reductions in medication use through 36 months.
- **Reduced Medication Dependence:** The study observed a notable decrease in the need for IOP-lowering medications, reducing patient dependence on adherence-prone therapies. The mean number of glaucoma medications used at baseline was 2.1 (1.5) and ranged from 1.1 to 1.6 medication classes between months 6 and 36, with statistically significant decreases in utilization through 18 months postoperatively ($p<0.0011$).

Paul Badawi, President and CEO of Sight Sciences added, "We are excited to see such compelling evidence highlighting OMNI's long-term impact. This study further strengthens the extensive body of clinical data that supports the safety and efficacy of the OMNI procedure. It reinforces our commitment to delivering innovative, data-driven interventional technologies that empower physicians to elevate patient care. OMNI continues to set new standards in minimally invasive glaucoma surgery, driving our mission to transform eyecare for the millions affected by glaucoma."

The OMNI Surgical System enables an implant-free, ab interno MIGS procedure intended to restore aqueous outflow of glaucomatous eyes by addressing the three areas of outflow resistance associated with the disease. This retrospective, observational cohort study of the procedure drew data from the IRIS Registry, the first comprehensive eye disease clinical registry in the United States. Launched in 2014, it has amassed over 851 million patient encounters and 80 million unique de-identified patients from nearly 30 electronic health records systems (EHRs) and 15,000 ophthalmologists and other eye care professionals across the U.S., as of July 1, 2024.

This study provides invaluable insights into the real-world effectiveness of OMNI, offering a crucial data-driven resource for ophthalmologists seeking to improve outcomes for patients with POAG.

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Paper Reference:

Radcliffe NM, Harris J, Garcia K, Zwick E, Chang RT, Mbagwu M. Standalone Canaloplasty and Trabeculotomy Using the OMNI Surgical System in Eyes with Primary Open-Angle Glaucoma: A 36-Month Analysis from the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight): Standalone Outcomes of Canaloplasty and Trabeculotomy. *Am J Ophthalmol*. Published online December 22, 2024. doi:10.1016/j.ajo.2024.12.015

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® 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 SION® Surgical Instrument is a bladeless, manually operated device used in ophthalmic surgical procedures to excise trabecular meshwork. The Company's TearCare® System 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. Visit www.sightsciences.com for more information.

The OMNI® Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma. Visit www.omnisurgical.com/ifu to access the instructions for use, warnings, precautions, and adverse event information.

About Verana Health

Verana Health® is a digital health company revolutionizing patient care and clinical research by utilizing physician expertise and artificial intelligence to unlock the true potential of real-world data. With exclusive access to the world's largest patient data sources in ophthalmology, urology and neurology, Verana Health is powering real-world evidence generation. Clinicians utilize these insights to improve the quality of care and quality of life for patients, and life sciences companies rely on the insights to accelerate the development of new therapies. For more information, visit www.veranahealth.com.

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