



## **Sight Sciences Announces First Patient Treated in TRIDENT European Trial to Evaluate the OMNI® Surgical System in Pseudophakic Eyes with Open-Angle Glaucoma**

March 24, 2022

**Novel trial design will compare safety and effectiveness outcomes for the OMNI Surgical System and the iStent inject® in lowering intraocular pressure (IOP) as a standalone treatment option without concomitant cataract surgery.**

MENLO PARK, Calif., March 24, 2022 (GLOBE NEWSWIRE) -- [Sight Sciences, Inc.](https://www.sightsciences.com) (Nasdaq: SGHT), an eyecare technology company focused on creating innovative solutions intended to transform care and improve patients' lives, today announced that the first patient has been treated in the novel TRIDENT clinical trial, designed to demonstrate the OMNI® Surgical System with higher volume as a safe and effective standalone treatment option, compared to implantation of iStent inject®, in lowering IOP in adult patients with open-angle glaucoma. With glaucoma, elevated IOP is the leading risk factor for the development and progression of the disease.

The TRIDENT study is a prospective, randomized, multicenter, comparative trial evaluating the safety and effectiveness outcomes, including IOP reduction, for pseudophakic eyes (eyes which had previously undergone cataract surgery) in three study arms: (1) canaloplasty alone using the OMNI Surgical System, (2) sequential canaloplasty followed by trabeculotomy using the OMNI Surgical System and (3) implantation of two trabecular microbypass canal implants using iStent Inject. The OMNI study arms will use a next-generation OMNI Surgical System that dispenses a higher volume of viscoelastic fluid than the currently marketed OMNI Surgical System. Study objectives include analyzing canaloplasty and trabeculotomy outcomes combined in one procedure and canaloplasty alone. This superiority trial will enroll 459 subjects who will be randomized in an equal allocation ratio (1:1:1) to the three study arms and followed for 12 months after surgery. To the best of our knowledge, TRIDENT is the largest standalone MIGS clinical trial ever initiated.

"Glaucoma is a progressive disease, and if left untreated or insufficiently treated, it can lead to irreversible disability and permanent vision loss. When determining a treatment plan for patients, it's imperative ophthalmologists have options available that could help patients who have previously undergone cataract surgery and need a tailored approach based on their disease state," said Karsten Klabe, MD, investigator. "The OMNI Surgical System is defining a new interventional treatment paradigm in glaucoma management. The novel TRIDENT study is an opportunity to seek additional evidence that it is a safe and effective option when addressing IOP in open-angle glaucoma in a broad patient population."

"The initiation of the TRIDENT study further illuminates our robust clinical pipeline and our pursuit to expand market access and use of the OMNI Surgical System that will ultimately increase the number of patients who could benefit from a MIGS procedure," said Paul Badawi, Co-Founder and CEO, Sight Sciences. "At Sight Sciences, our team is committed to pioneering novel clinical studies that will provide new clinical evidence for glaucoma management with the ultimate goal of improving the lives of patients impacted by this sight-threatening disease. Current surgical treatment options for canaloplasty alone are limited, and we are excited to take this impactful step forward in clinical research."

The OMNI Surgical System is an implant-free MIGS device that allows physicians to perform two procedures (canaloplasty and trabeculotomy) that target the three primary points of resistance in the conventional outflow pathway with one intelligent device. The OMNI Surgical System is cleared for canaloplasty followed by trabeculotomy to reduce IOP in adult patients with primary open-angle glaucoma (POAG) (FDA) and open-angle glaucoma (CE).\*

### **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 physicians to address the leading cause of dry eye disease.

For more information, visit [www.sightsciences.com](https://www.sightsciences.com)

### **About the OMNI® Surgical System**

The OMNI® Surgical System is a handheld, single-use therapeutic device for minimally invasive glaucoma surgery (MIGS). It is indicated for canaloplasty (the microcatheterization and viscodilation of Schlemm's canal) followed by trabeculotomy (the cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma. OMNI® allows surgeons to access 360 degrees and three primary points of resistance of an eye's diseased conventional outflow pathway (trabecular meshwork, Schlemm's canal, and collector channels) through a single clear corneal microincision.

\*OMNI® is indicated by the FDA for canaloplasty (the microcatheterization and viscodilation of Schlemm's canal) followed by trabeculotomy (the cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma. OMNI has a CE Mark for the

catheterization and transluminal viscodilation of Schlemm's canal and the cutting of trabecular meshwork to reduce intraocular pressure in adult patients with open-angle glaucoma.

OMNI<sup>®</sup> should not be used in any situations where the iridocorneal angle is compromised or has been damaged since it may not be possible to visualize the angle or to properly pass the microcatheter. Do not use the OMNI<sup>®</sup> in patients with angle recession; neovascular glaucoma; chronic angle closure; narrow-angle glaucoma; traumatic or malignant glaucoma; or narrow inlet canals with plateau iris or in quadrants with previous MIGS implants.

OMNI<sup>®</sup> received its first FDA clearance in 2017 and is protected by a global patent portfolio including 32 issued patents worldwide.

OMNI<sup>®</sup> is a registered trademark of Sight Sciences.

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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 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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