Sight Sciences Announces FDA Authorization for the PRECISION Trial, a Groundbreaking Three-Arm Randomized, Controlled IDE Trial of Canal Viscodilation in Combination with Cataract Surgery in Adults with Primary Open-Angle Glaucoma (POAG)

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As the pioneer of ab interno canaloplasty, Sight Sciences is executing this IDE trial to seek FDA clearance for canal viscodilation alone as a MIGS procedure for adults with POAG

MENLO PARK, Calif., Nov. 10, 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 that the Food and Drug Administration (FDA) has granted an Investigational Device Exemption (IDE) authorizing the Company to conduct a clinical study to assess the safety and effectiveness of a new, higher volume (21 microliters of viscoelastic fluid dispensed), investigational OMNI® device ("higher volume OMNI") to perform canal viscodilation alone to lower intraocular pressure (IOP) in adults with primary open-angle glaucoma (POAG).

The PRECISION clinical trial is designed as a three-armed randomized controlled trial (RCT), which the Company believes will be the first of its kind and represents the largest MIGS clinical trial ever initiated, based on total number of patients receiving MIGS interventions in conjunction with cataract surgery (n=459). The devices that will be evaluated in the study are the higher volume OMNI (Sight Sciences) and the iStent Inject Canal Implant (Glaukos). In the three arms of the study, patients will receive one of the following treatments in conjunction with cataract surgery: (1) *ab interno* canaloplasty alone using higher volume OMNI; (2) sequential canaloplasty followed by trabeculotomy using higher volume OMNI; or (3) implantation of two trabecular microbypass canal implants using iStent Inject.

The PRECISION study is intended to evaluate for regulatory purposes the safety and efficacy of higher volume OMNI for use in canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) without sequential trabeculotomy (cutting of trabecular meshwork (TM)) for IOP and medication reduction in adult patients with POAG. The higher volume OMNI is a next-generation OMNI device that dispenses a higher volume of viscoelastic fluid (21 microliters) than the currently marketed OMNI Surgical System (11 microliters). Sight Sciences is conducting this canal viscodilation alone IDE trial, which is believed to be necessary to support a premarket notification to the FDA seeking clearance for use to perform canal viscodilation alone procedures in adults with POAG.

"I'm excited to begin this prospective study evaluating the safety and efficacy of standalone *ab interno* canaloplasty using the higher volume OMNI," said Mark Gallardo, M.D., El Paso Eye Surgeons, principal investigator of the PRECISION clinical trial. "The higher volume (21 microliters versus 11 microliters) of viscoelastic may provide for a greater expansion of Schlemm's canal and the distal collector system, which in turn may allow for enhanced aqueous outflow with a resultant reduction in pressure. This procedure can become a valuable first-line MIGS procedure for adults with mild to moderate POAG. When more significant pressure and medication reductions are necessary, comprehensively addressing all three points of outflow resistance by coupling canaloplasty with trabeculotomy, may synergistically allow patients to achieve their targeted goals."

"We believe in our technology, including the potential of the higher volume OMNI to address unmet medical needs in POAG patients, and we are excited to develop robust clinical data under this IDE that could support an expanded indication for use for canal viscodilation alone without trabeculotomy," said Paul Badawi, Co-Founder and CEO, Sight Sciences. "Compelling, multi-center safety and effectiveness clinical data was necessary for FDA 510(k) clearance of our current combined OMNI indication for use in canaloplasty and trabeculotomy. We are now making the next requisite clinical investments under this IDE to provide the FDA with robust clinical data that could support the safety and effectiveness of a canaloplasty alone indication. We believe that, with the FDA's authorization to proceed with the PRECISION IDE trial, we will be the first to investigate a MIGS device for use to lower IOP using *ab interno* transluminal canal viscodilation, or *ab interno* canaloplasty, alone. This trial is the next step in our path to set the clinical standards of canal viscodilation as a MIGS procedure for POAG. We are very pleased and appreciative of the collaborative IDE process with the FDA and look forward to developing the clinical data necessary to seek clearance for this new specific MIGS indication for the *ab interno* transluminal viscodilation of Schlemm's canal, which we believe could meaningfully benefit adult patients with POAG in the future."

About Sight Sciences

Sight Sciences is an eyecare technology company focused on developing and commercializing innovative solutions intended to transform standards of 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 commercially available today as a wearable, office-based thermal eyelid technology that enables the controlled application of localized heat to the eyelids. The Company has a 510(k) pending for the clearance of the TearCare System for an expanded indication for the application of localized heat therapy in adult patients with evaporative dry eye disease due to meibomian gland dysfunction (MGD). For more information, visit www.sightsciences.com.

About OMNI®

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 POAG. OMNI allows surgeons to access 360 degrees and all 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.

The OMNI Surgical System hould 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 OMNI 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.

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 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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