

# Second Sight Announces Positive Five-Year Data from Argus II Retinal Prosthesis System

Study Results Published in *Ophthalmology* Show Safety and Sustained Improvement in Visual Performance for Blind Patients

SYLMAR, Calif.--(BUSINESS WIRE)-- Second Sight Medical Products, Inc. (NASDAQ:EYES) ("Second Sight"), the developer, manufacturer and marketer of implantable visual prosthetics that provide some useful vision to blind patients, today announced positive five-year outcomes associated with patients using the Argus® II Retinal Prosthesis System ("Argus II"). The Argus II captures images on an eyeglass-mounted miniature video camera, converts the images to electrical pulses, and then transmits those pulses wirelessly to electrodes implanted on the retinal surface, bypassing defunct retinal cells and stimulating the viable retinal cells in patients with severe to profound retinitis pigmentosa (RP).

The paper entitled "Five year safety and performance results from the Argus II Retinal Prosthesis System Clinical Trial" follows the assessment of 30 subjects in the clinical trial (NCT00407602) implanted with the Argus II in 10 centers throughout the United States and Europe. All patients were blind (i.e., with bare light perception or worse) from RP or similar disorders. Throughout five years of clinical study, results showed that patients' visual function improved after implantation with the Argus II and these improvements were sustained over five years. Patients reported that using Argus II had a positive impact on their wellbeing, including a renewed connection with loved ones and the world around them. Results also demonstrated that the Argus II had an acceptable safety profile.

"For patients with RP who are living in darkness, the long-term benefits of the Argus II in restoring some useful vision represents a very meaningful milestone," said Lyndon da Cruz, MD, PhD, Consultant Retinal Surgeon at Moorfields Eye Hospital NHS Foundation Trust and lead author for the study. "Perhaps most exciting is the proven ability of the Argus II to increase patients' functional vision. With the Argus II, patients can perform tasks that would not be possible without the device. This can be a life-altering change. It is good that we have now shown that these changes last for many years after implantation."

"We are excited to see that the substantial visual improvement gained from the Argus II endures over five years – promising news for patients blinded by RP, as well as for our company's continued efforts to restore vision," said Will McGuire, President and CEO of Second Sight. "The study supports the long-term safety profile and benefit of the Argus II system, and these results will continue to drive our approach in the future, both in the development process and in seeking additional regulatory and reimbursement approvals for

# the Argus II."

In the Argus II study, three types of visual function tests were performed using computer-run assessments: square localization (i.e. object detection), direction of motion (i.e. motion detection) and discrimination of oriented gratings (i.e. visual acuity). Two types of real-world orientation and mobility (O&M) tests were also performed: one test asked patients to locate and touch a door, and the second test asked patients to follow a white line on the floor. The ability to find a door and follow a line have real-world meaning with respect to mobility, ambulation and safety.

Earlier results from this trial were used to gain FDA approval of the Argus II in addition to CE Mark in Europe. The Argus II is the first and only retinal implant to have both approvals, and is the only system to have demonstrated long-term reliability and benefit. Today, over 200 patients have been treated with the Argus II.

Positive results of this long-term clinical study follow news about the Argus II's long-term cost effectiveness published in 2014. Researchers evaluated the costs of using the Argus II over 25 years beginning at age 46 (the estimated average age that patients with RP are diagnosed as legally blind) and found that the incremental cost per ratios for the Argus II were about 16,000 US Dollars/quality-adjusted life year – well below payers' cost utility thresholds and costs of "care as usual." <sup>2,3</sup>

Current research efforts by Second Sight include a feasibility study of the Argus II for individuals with dry age-related macular degeneration; hardware and software upgrades for existing and future Argus II patients; and the development of an advanced visual prosthesis, the Orion™ I Visual Cortical Prosthesis, aimed at patients with nearly all other forms of blindness.

## **About the Argus® II Retinal Prosthesis System**

Second Sight's Argus II System provides electrical stimulation that bypasses the defunct retinal cells and stimulates remaining viable cells inducing visual perception in individuals with severe to profound retinitis pigmentosa (RP). The Argus II works by converting images captured by a miniature video camera mounted on the patient's glasses into a series of small electrical pulses, which are transmitted wirelessly to an array of electrodes implanted on the surface of the retina. These pulses are intended to stimulate the retina's remaining cells, resulting in the perception of patterns of light in the brain. The patient then learns to interpret these visual patterns, thereby regaining some useful vision. The system is controlled by software and is upgradeable, which may provide improved performance as new algorithms are developed and tested. The Argus II is the first artificial retina to receive widespread approval, and is offered at approved centers in Austria, Canada, France, Germany, Italy, Netherlands, Saudi Arabia, Spain, Switzerland, Turkey, United Kingdom and the United States.

#### **About Second Sight**

Second Sight's mission is to develop, manufacture and market innovative implantable visual prosthetics to enable blind individuals to achieve greater independence. Second Sight has developed and now manufactures and markets the Argus® II Retinal Prosthesis System. Enrollment has been completed in a feasibility trial to test the safety and utility of the Argus II

in individuals with Dry Age-Related Macular Degeneration. Second Sight is also developing the Orion™ I Visual Cortical Prosthesis to restore some vision to individuals who are blind due to causes other than preventable or treatable conditions. U.S. Headquarters are in Sylmar, California, and European Headquarters are in Lausanne, Switzerland. For more information, visit www.secondsight.com.

#### Safe Harbor

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange and Exchange Act of 1934, as amended, which are intended to be covered by the "safe harbor" created by those sections. All statements in this release that are not based on historical fact are "forward looking statements." These statements may be identified by words such as "estimates," "anticipates," "projects," "plans," or "planned," "seeks," "may," "will," "expects," "intends," "believes," "should" and similar expressions or the negative versions thereof and which also may be identified by their context. All statements that address operating performance or events or developments that Second Sight expects or anticipates will occur in the future are forward-looking statements. While management has based any forward looking statements included in this release on its current expectations, the information on which such expectations were based may change. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our Annual Report on Form 10-K as filed on March 17, 2015 and our other reports filed from time to time with the Securities and Exchange Commission. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should however review additional disclosures we make in our registration statement on Form S-1 for this offering that has been filed with the Securities and Exchange Commission, as well as our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

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<sup>&</sup>lt;sup>1</sup> The paper was electronically published today prior to publication in Ophthalmology.

<sup>&</sup>lt;sup>2</sup> Vaidya A, Borgonovi E, Taylor RS, et al. The cost-effectiveness of the Argus II retinal prosthesis in Retinitis Pigmentosa patients. BMC Ophthalmol. 2014;14:49.

<sup>&</sup>lt;sup>3</sup> 16,000 US Dollars has been calculated from 14,603 Euros noted in the paper based on the conversion rate in July 2016

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