FDA Panel Recommends FDA Approval for Second Sight’s Argus® II Retinal Prosthesis System

The Associated Press

SYLMAR, Calif.--(BUSINESS WIRE)--Oct 1, 2012--On Friday September 28 th, a U.S. Food and Drug Administration (FDA) Ophthalmic Devices Advisory Panel unanimously voted 19-0 that the probable benefit of the Argus II Retinal Prosthesis System outweighs the risks to health, an important step toward the FDA market approval of this product manufactured by Second Sight Medical Products, Inc. In making this determination, the panel spent ten hours carefully reviewing and discussing data submitted from the international clinical trial of this innovative retinal implant that, for the first time ever, partially restores vision to patients who are blind due to Retinitis Pigmentosa (RP).

“I am very pleased with the panel recommendation today. The panel deliberations were well informed and thorough and their decision validated over two decades of work by Second Sight and our collaborators,” said Robert Greenberg, MD, PhD, President and CEO of Second Sight. “I would also like to thank all of the people around the world with RP who volunteered to participate in our clinical trials, and the doctors who treated them. Without their pioneering efforts, today’s result would not have been possible.” The panel, which was comprised of 19 voting members (23 members total) with expertise in ophthalmology, retinal disease, low vision, electrophysiology and other specialties heard testimony from the sponsor, FDA, and several doctors and participants involved in the most recent clinical trial that began in 2007. After hearing the testimony, asking questions, discussing concerns, and carefully deliberating, they voted unanimously that the probable benefit of the Argus II Retinal Prosthesis System outweighs the risks to health.

“We are looking forward to working with the FDA now to quickly get the product approved,” stated Anne-Marie Ripley, Vice President of Clinical and Regulatory Affairs at Second Sight. “There is no therapy available currently for these patients and we would like to make Argus II available to American doctors and their patients as soon as possible.” This recommendation came after more than 20 years of work in the field, three clinical trials, over $100M in public investment by the National Eye Institute, the Department of Energy, and the National Science Foundation, and an additional $100M in private investment. Many of the hundreds of people that have played instrumental roles in the development of Argus II were moved by the panel result.

"This is a truly exciting and historic moment for people with advanced inherited retinal degenerations such as retinitis pigmentosa," said Dr. Stephen Rose, Chief Research Officer, Foundation Fighting Blindness, which helped get the project started with early support. "The Argus II has the potential to provide life-changing vision capabilities, and we are delighted to see the prosthesis make a big step toward FDA approval and getting out to the people with severe vision loss who can

benefit from it." "Modest gains in vision can make a big difference to a person blinded by retinitis pigmentosa," added Dr. Paul Sieving, Director of the National Eye Institute. "The Argus II retinal prosthesis allows users to reclaim their independence and improve their lives. The NEI is proud to have provided support to Second Sight to make the Argus II a reality." Besides Dr. Greenberg, and Ms. Ripley, panel presenters and responders on behalf of the sponsor included Dr. Lyndon da Cruz (Consultant Retinal Surgeon, Moorfields Eye Hospital, London, UK), Dr. Julia Haller (Ophthalmologist in Chief, Wills Eye Institute, Philadelphia), Dr. Gislin Dagnelie (Associate Professor of Ophthalmology, Johns Hopkins University, Baltimore), Dr. Suber Huang (Vice-Chair Department of Ophthalmology and Visual Sciences, Case Western Reserve University, Cleveland), Dr. Eugene de Juan (Jean Kelly Stock Distinguished Professor of Ophthalmology, UC San Francisco), Dr. Duane Geruschat (Research Associate, Johns Hopkins Wilmer Eye Institute, Baltimore), and Dr. Mark Humayun (Professor of Ophthalmology, Biomedical Engineering, Cell and Neurobiology, Doheny Eye Institute, Los Angeles).

About Retinitis Pigmentosa RP, an inherited retinal degenerative disease that often results in nearly complete blindness, affects roughly 100,000 Americans and has been designated by the World Health Organization as an orphan disease. In 2009, the Argus II, which is intended to help the worst affected RP patients, received a Humanitarian Use Designation (HUD), making it a candidate for an HDE approval which is intended to expedite the market introduction of technologies intended to treat smaller, underserved patient populations.

About Argus II The Argus II system works by converting video images captured by a miniature camera, housed in the patient's glasses, into a series of small electrical pulses that are transmitted wirelessly to an array of electrodes on the surface of the retina. These pulses are intended to stimulate the retina's remaining cells resulting in the corresponding perception of patterns of light in the brain. Patients then learn to interpret these visual patterns thereby regaining some visual function. Second Sight gained European approval (CE Mark) for the system in 2011 – the first and only approval of a retinal prosthesis anywhere in the world. With this overwhelming vote of confidence from the medical community, the company will now turn its attention to ensuring that Argus II becomes the first ever approved retinal prosthesis in the US.

About Second Sight Second Sight Medical Products Inc., located in Los Angeles, California, was founded in 1998 to create a retinal prosthesis to provide sight to patients blinded from outer retinal degenerations, such as Retinitis Pigmentosa. Through dedication and innovation, Second Sight's mission is to develop, manufacture and market implantable visual prosthetics to enable blind individuals to achieve greater independence. While the Argus II system is CE-marked in Europe it is not yet approved for sale in the United States. European Headquarters are in Lausanne, Switzerland. For more information, go to www.2-sight.com [1].

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