Second Sight Medical Products Receives FDA Approval for Argus II System

Argus® II Retinal Prosthesis System is the first approved bionic eye in the US with life-changing potential for the treatment of blindness due to retinitis pigmentosa

SYLMAR, Calif.--(BUSINESS WIRE)--After more than 20 years of research and development, Second Sight Medical Products, Inc., the leading developer of retinal prostheses for the blind, is pleased to announce that its Argus® II Retinal Prosthesis System ("Argus II") has received U.S. market approval from the Food and Drug Administration (FDA) to treat individuals with late stage Retinitis Pigmentosa (RP). This announcement follows receipt of the European approval in 2011, and a unanimous recommendation by the FDA's Ophthalmic Devices Advisory Panel in September 2012 that this revolutionary product be made available to treat this patient population in the U.S.

"The Argus II has the potential to provide life-changing vision capabilities as well as increased mobility and independence."

"We are thrilled to be able to offer the only FDA-approved long-term therapy for people suffering from advanced RP," said Robert Greenberg, MD, PhD, President and CEO of Second Sight. "With this approval, we look forward to building a strong surgical network in the United States and recruiting new hospitals that will offer the Argus II retinal implant. This is a game changer in sight-affecting diseases, that represents a huge step forward for the field and for these patients who were without any available treatment options until now."

Argus II is intended to provide electrical stimulation of the retina to induce visual perception in blind individuals with retinitis pigmentosa and has the capacity to offer life-changing visual capabilities to those currently unable to see anything except, at best, extremely bright lights.

Although the resulting vision is not the same as when these patients had normal vision, investigators involved in the clinical trial of the Argus II are eager about the approval. "It is incredibly exciting to have FDA approval to begin implanting the Argus II and provide some restoration of vision to patients blinded from RP. In the patients that have been implanted to date, the improvement in the quality of life has been invaluable," said Mark Humayun, MD, PhD, Cornelius Pings Professor of Biomedical Engineering and Professor of Ophthalmology, Biomedical Engineering, Cell and Neurobiology, Keck School of Medicine of USC and USC Viterbi School of Engineering, University of Southern California.

"The fact that many patients can use the Argus implant in their activities of daily living such as recognizing large letters, locating the position of objects, and more, has been beyond our wildest dreams, yet the promise to the patients is real and we expect it only to improve over time."

With approval from the FDA, the Argus II is slated to be available later this year in clinical centers across the country. Second Sight will be actively adding sites to make the therapy more readily available and encourages interested facilities and patients to contact them.

“This is an exciting time for people who are blind from RP. Second Sight’s prosthetic retinal device brings meaningful hope to tens of thousands of people with advanced retinal diseases,” said Stephen Rose PhD, chief research officer at Foundation Fighting Blindness. He adds, “The Argus II has the potential to provide life-changing vision capabilities as well as increased mobility and independence.”

FDA approval came following more than 20 years of work in the field, two 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 investments.

About Retinitis Pigmentosa (RP)

RP, an inherited retinal degenerative disease that often results in nearly complete blindness, affects roughly 100,000 Americans. The Argus II System is intended to help the worst-affected RP patients, and this approval was made under a Humanitarian Device Exemption intended to expedite market introduction of technologies intended to treat smaller, underserved patient populations.

About the Argus II System

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. The patient then learns to interpret these visual patterns thereby regaining some visual function. Second Sight gained European approval (CE Mark) for the system in 2011 and FDA approval in 2013. It remains the first and only approved retinal prosthesis anywhere in the world.

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 RP. 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. US Headquarters are in Sylmar, CA, and European Headquarters are in Lausanne, Switzerland. For more information, visit www.2-sight.com.

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