First U.S. artificial retina approved; device could restore some sight to blind

By Brady Dennis and Lena H. Sun, Published: February 15

The Food and Drug Administration on Thursday approved the nation’s first “artificial retina,” a highly anticipated advance that could give limited vision to adults rendered blind by a rare genetic disorder.

The new device could make it possible for certain patients to regain the ability to do simple but significant tasks, such as recognizing words on a page, detecting street signs and matching pairs of socks.

“For someone who can’t see, it’s a life changer to suddenly be able to walk into a room and see where the door is,” said Brian Mansfield, deputy chief research officer at the Foundation Fighting Blindness, which describes itself as the largest private organization funding such research.

The approval marks a milestone in the research of retinal diseases, which affect millions of Americans. A growing number of potential treatments for the ailments include stem cells, gene therapy, pharmaceuticals and surgical procedures.

The device, which received approval from European regulators in 2011 and has been implanted in more than 50 patients overseas, is designed for adults with advanced retinitis pigmentosa, a rare genetic condition that in the United States affects about 100,000 people. The condition damages the light-sensitive cells that line the retina. In time, a person’s limited ability to tell light from dark can erode, and often the outcome is total blindness.

“It’s a horrendous disease,” said Robert Greenberg, chief executive of Second Sight, the California-based company that has been developing the Argus II retinal prosthesis for two decades. “Their visual world closes in on them gradually until they are completely blind.”

The Argus II system approved Thursday includes a surgically implanted artificial retina about the size of an aspirin and with about 55 electrodes. Patients then are outfitted with a pair of eyeglasses with a small video camera and video processor. Together, the components transform images from the video camera into data that is transmitted to the brain through the implanted retina.

“It’s a game-changer in a lot of ways,” Greenberg said. “To go from complete darkness to being able to identify letters and words, it’s a pretty significant step.”
Currently, the technology allows patients only to see shades of gray. Greenberg said his company is developing artificial retinas that will provide both higher-resolution and color images and ones to help a wider array of patients with little or no vision.

Thursday’s news drew a jubilant reaction from patients who stand to benefit from the technology, either now or in the future.

“I think this could lead, in a very few years, to a fundamental revolution that will end many forms of blindness as a disability,” said Karen Shaw Petrou, 59, a Washington banking consultant who has a type of retinal degenerative disease and relies on a guide dog to navigate the city.

Petrou still has some sight and isn’t eligible yet to have the new implant in her eye, but like others, she hopes that she could benefit if the FDA approves wider use of the device.

She said an artificial retina has the potential to “reach not just the limited class of the totally blind, but across the spectrum of many people with different types of blinding disorders.”

Elias Konstantopoulos, 74, a retired electrician who lives in Glen Burnie, said he was 99 percent blind before he had the artificial retina implanted in 2009 as part of a clinical trial. The biggest difference it has made for him, he said, is allowing him to detect motion.

If someone is standing in front of him, he can now tell if the person is moving to the right or to the left. “I can tell something is moving and see which direction,” he said. He can also see the shape of a dark door against a white wall.

“When you have nothing, it’s something. So it’s a lot of hope,” Konstantopoulos said, although he hopes the technology will improve enough to let him see things in more detail, such the face of his 3 1/2-year-old grandson.

An FDA blog post Thursday shared comments of other patients. One person was able to see the crosswalk lines on Manhattan streets. Another man could see a glimpse of his 17-year-old son. “I mean, how happy that made me, not only to see the silhouette of my son, but to hear that voice coming and saying: ‘Yeah, it’s me, Dad. I’m here, and I love you.’ ”

The device costs about $100,000 in Europe and is covered by insurance plans there, said Greenberg, who began developing the artificial retina in the 1990s while studying at Johns Hopkins University. He said he expects that the device will be priced higher in the United States when it becomes available this year. The company also is asking Medicare to cover the device.

The surgery to implant the device takes about two hours and can be done by any qualified retinal surgeon. Greenberg said he expects that the procedure initially will be available at about 10 clinical centers across the country, with more coming online in the future.

The FDA approved the Argus II as a “humanitarian use” device, limited to products that treat fewer than 4,000 people in the United States each year. To receive such an approval, a company must demonstrate that the device is safe and that its probable benefits outweigh any risk of illness or injury. The company also must show that no comparable device exists to treat the condition.

The FDA reviewed data that included a clinical study of 30 patients outfitted with the artificial retina system. Results showed that nearly two-thirds of patients had no adverse effects from the surgery, and most were able to perform basic activities better with the artificial retina than without. Among them: Detecting the
direction of motion, recognizing letters and words, walking down a sidewalk without stepping off the edges, and correctly matching black, gray and white socks.

Several government organizations, including the Department of Energy and the National Institutes of Health, together provided more than $100 million in grant funding to support development of the new technology.

“For many of the approximately 1,300 individuals who will develop the disease this year, this technology may change their lives,” William H. Maisel, deputy director for science and chief scientist at the FDA’s Center for Devices and Radiological Health, wrote in an agency blog post Thursday. “It’s the difference between night and day.”

Sponsored Links

Hot Stock Pick NTRR
Breaks into New Industry, Price Could Double–Learn More!
www.OTCStockPick.com

AGIN Stock
Has AGIN Become the Perfect Stock?
graphenestock.net/trends-agin/

Get Athena Pheromones
Enjoy more affection! Biologist Winnifred Cutler's unscented formulas.
www.athenainstitute.com

© The Washington Post Company