BIONIC VISION
TECHNOLOGIES

Bionic Vision Technologies Announces Interim Pilot Study Results of the BVT Bionic Eye System Designed to Help the Blind Achieve Greater Mobility and Independence

– Up to 44-Week Data Shows Significant Improvement in Both Obstacle Awareness and Object Detection –

San Francisco, Ca, Jan. 13, 2020 - Bionic Vision Technologies today announced the interim results of a pilot study involving four patients with late-stage Retinitis Pigmentosa (RP) implanted with a visual prosthesis designed to improve awareness of external objects and patient surroundings. Results presented during the 38th Annual JP Morgan Conference in San Francisco demonstrated improved combined performance of all six functional vision tests at 44 weeks of active use of the device.

"These outcomes represent a significant milestone for Bionic Vision Technologies and give hope to many patients who have lost their sight due to late-stage RP," said Ash Attia, CEO. "Based on these positive results, BVT intends to initiate a worldwide clinical trial for the commercialization of our Gen3 device which will offer improved performance and usability as well as a streamlined external design, similar to the appearance of traditional eyeglasses."

This current two-year pilot study, being conducted at the Centre for Eye Research Australia (CERA) and the Bionics Institute in Melbourne, Australia, involves four adult participants with near total blindness caused by the inherited retinal disease, Retinitis Pigmentosa. Each study participant was unilaterally implanted with the BVT Gen2 suprachoroidal visual prosthesis in the eye with the least remaining vision. Mobility testing was initiated after a two-month surgical healing period followed by a 16-week period of vision rehabilitation training. Participants were asked to complete a series of six tests at 17 weeks following training and then at three monthly intervals from week 20 with the device turned both "on" and "off" to assess performance. Data has been collected up to at 44 weeks for all patients and will continue to be collected for up to 104 weeks.

Of all mobility tests conducted, the most significant improvement in this cohort was observed with the Primary Obstacle Avoidance Task, which relies on participants identifying obstacles in their pathway. At 44 weeks, patients detected 74.3% of obstacles when the device was turned on, compared to only up to 4% of obstacles when the device was turned off. Considerable improvement was also recorded for the Location Task which relies on study participants identifying and touching an object similar to the shape of a window on a wall. At 44 weeks, subjects were able to locate and touch the window 70.3% of the time when the device was turned on, compared to only up to 24.4% of the time when the device was turned off. The average touching distance from the window was also improved from 78cm to 14cm signally improved accuracy.

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"This 44-week combined report gives us important new insight about the real-world use of the Bionic Eye System," said Associate Professor Penelope Allen, MD, Principal Investigator and Head of the Vitreoretinal Unit at CERA and the Royal Victorian Eye and Ear Hospital. "The data from this trial demonstrates that the longer patients use the system, the more proficient they become at locating objects, recognizing doorways and avoiding obstacles − all of which contribute to a greater sense of mobility and independence in the day-to-day lives of people who are blind. The device also gives patients a better sense of social connection, something they have missed since the loss of their sight."

"In addition, patients are reporting that they can do things they have not been able to do for many years. Our research team is encouraged by the unique progress that each patient is making and we believe there will be continued progress the longer patients learn to use the Bionic Eye system."

Prof. Allen added, "We are also encouraged that after a year of being implanted, all four of the visual prostheses have remained securely in place within the suprachoroidal space without the need for additional surgery. The stability and lack of serious adverse events of this implant is a clear advantage compared to other visual prosthesis technologies that have been commercialized to date."

About the BVT Bionic Eye

BVT's Bionic Eye System consists of a wearable device and a visual implant similar in concept and design to that used by cochlear hearing implants. It operates by translating images from a camera mounted on an eyeglass frame into electrical signals which stimulate the nerves via electrodes placed behind the patient's eye to deliver visual information to the brain. Implanting the electrodes in the suprachoroidal space (between the choroid and the sclera), as opposed to sub-retinal or epi-retinal implantation, avoids damage to an already compromised retina. Because the implant is placed behind the retina and does not make contact with the retina, patients may still be able to participate in gene, stem cell or other future therapies.

Since 2012, a total of seven patients have received the BVT Bionic Eye suprachoroidal implant at the Royal Victorian Eye and Ear Hospital and the Centre for Eye Research Australia, Victoria, Australia. The Gen1 Bionic Eye System, using a non-implantable percutaneous connector, was implanted in three patients for a 12-month monitoring period in an Initial Proof of Concept/First in Human Phase I Study.[1] The Gen2 fully-implantable Bionic Eye System is currently being investigated in four RP patients in a two-year pilot study. No device-related serious adverse events have been reported in either Gen1 or Gen2 studies. BVT is now developing the Gen3 Bionic Eye System which will incorporate new software algorithms, including automatically adjusting to environmental lighting conditions. The external device will be smaller, lighter and look more like traditional eyeglasses to enhance patient comfort and social interaction.

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[1] L.N. Ayton, et al.First-in-human trial of a novel suprachoroidal retinal prosthesis PLoS One, 9 (12) (2014), p. e115239, 10.1371/journal.pone.0115239

About Retinitis Pigmentosa

Retinitis Pigmentosa refers to inherited eye disorders involving gradual loss of photoreceptor cells in the retina. This causes a gradual degeneration of sight, particularly of peripheral vision, resulting in tunnel vision and eventually complete blindness in some people. Damaged photoreceptor cells (rods and cones) leave the retina unable to process and transmit visual information. With a prevalence of one in 4000 people, Retinitis Pigmentosa affects approximately 2 million people and is the predominant cause of inherited blindness[2].

About Bionic Vision Technologies

Bionic Vision Technologies, Pty., Ltd. (BVT) is a privately held Australian company developing the Bionic Eye System, a visual prothesis designed to restore functional vision to the blind suffering from inherited retinal diseases, such as Retinitis Pigmentosa (RP). To date, the Company has completed initial human testing in seven RP patients to demonstrate safety and initial efficacy with positive outcomes in patient mobility and device stability/durability. BVT intends to initiate a worldwide clinical trial in key markets, including Australia, USA and Europe, with commercialization anticipated soon after. BVT is collaborating with some of Australia's leading research organizations, including The Centre for Eye Research Australia, The Bionics Institute, CSIRO's Data61, The University of Melbourne and The Australian National University. For more information about Bionic Vision Technologies, please visit: https://www.bionicvis.com.

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[2] National Institute of Health: https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/retinitis-pigmentosa