Pixium Vision announces new compelling results with Prima System demonstrating integration of prosthetic and natural vision

- Data mark a major step forward in treatment of atrophic AMD
- Results confirm the safety and stability of the Prima System implant over 24-30 months follow-up
- Prima System pivotal PRIMAvera study ongoing

Paris, France, March 30 2021 - CET– Pixium Vision SA (Euronext Growth Paris - FR0011950641), a bioelectronics company that develops innovative bionic vision systems to enable patients who have lost their sight to live more independent lives, announces the pre-publication of a paper outlining the clinical results with its New Generation Prima System, a photovoltaic substitute of photoreceptors providing simultaneous use of the central prosthetic and peripheral natural vision in atrophic dry age-related macular degeneration (AMD).

“These important results from the French clinical study show that patients could simultaneously use prosthetic central vision generated with the Prima System and their remaining peripheral vision - an important step forward validating the Prima System as a treatment for dry AMD,” said José-Alain Sahel, M.D., University of Pittsburgh School of Medicine and a co-founder of Pixium Vision. “The very consistent letter acuity together with the stable implant performance over the 24 months follow-up, provide great confidence in this technology and indicate the benefit the Prima System could bring to patients with no other treatment option.”

The paper entitled “Simultaneous Perception of Prosthetic and Natural Vision in AMD Patients” outlines how four patients with geographic atrophy and subretinally implanted with the wireless device in a French feasibility study use the newly developed transparent glasses of the Prima System. For the first time, these patients demonstrated concurrent use of the central prosthetic and peripheral natural vision. The results confirmed the safety and stability of the PRIMA implant over 24-30 months follow-up and indicated that further advancements in the photovoltaic pixel design, video glasses and image processing would lead to even more functional restoration of sight.

Using electronic magnification, which allows zoom-in up to a factor of 8x, patients gained visual acuity in the range of 20/63-20/98, greatly exceeding the threshold of legal blindness (20/200). The acuity among all the patients was very consistent (20/438-20/564 without magnification) and very close to the pixel size (1.04 – 1.34 pixels).

“Simultaneous use of the prosthetic central vision and the natural peripheral vision in both the implanted eye and the fellow eye is a very important feature of the Prima System for patients with geographic atrophy and is essential for improving their quality of life,” said Prof. Daniel Palanker, PhD, of Stanford University, one of the authors of the article and a scientific advisor to Pixium Vision.

Loss of photoreceptors in atrophic AMD results in severe visual impairment. Since the low-resolution peripheral vision is retained in such conditions, restoration of central vision should not jeopardize the surrounding healthy retina and allow for simultaneous use of the natural and prosthetic sight. The Prima System implant is designed to substitute the lost photoreceptors by electrically stimulating the secondary neurons in the retina, which in turn transmit the visual information via the rest of the retinal circuits to the brain.

The full abstract is available online here.

Pixium’s Next Generation Prima System is currently being studied in the PRIMAvera study, a pivotal study to confirm the safety and benefits of the Prima System prior to market approval in Europe. The study was initiated
in Q4 2020 and is an open-label, baseline-controlled, nonrandomized, multi-center, prospective, single-arm confirmatory trial that will evaluate the Prima System in 38 patients.

About Pixium Vision

Pixium Vision is creating a world of bionic vision for those who have lost their sight, enabling them to regain visual perception and greater autonomy. Pixium Vision’s bionic vision systems are associated with a surgical intervention and a rehabilitation period. Prima System sub-retinal miniature photovoltaic wireless implant is in clinical testing for patients who have lost their sight due to outer retinal degeneration, initially for atrophic dry age-related macular degeneration (AMD). Pixium Vision collaborates closely with academic and research partners, including some of the most prestigious vision research institutions in the world, such as Stanford University in California, Institut de la Vision in Paris, Moorfields Eye Hospital in London, Institute of Ocular Microsurgery (IMO) in Barcelona, University hospital in Bonn, and UPMC in Pittsburgh, PA. The company is EN ISO 13485 certified and qualifies as “Entreprise Innovante” by Bpifrance.

For more information: http://www.pixium-vision.com/fr
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