



## **Pixium Vision announces positive review of the first results with PRIMA, its wireless subretinal implant, in patients with atrophic Dry-AMD**

- PRIMA could be safely implanted
- In all five patients, implants were successfully activated
- Training helps to improve quality of visual perception

**Paris, France. September 24, 2018** – 6.00 PM CEST - Pixium Vision (FR0011950641 - PIX), a bioelectronics company developing innovative bionic vision systems to enable patients who have lost their sight to lead more independent lives, announced the positive review of the first clinical results of PRIMA, its miniature wireless photovoltaic sub-retinal implant, by the Medical Advisory Board members and study investigators during the EURETINA Conference in Vienna, Austria. These results<sup>1</sup> were presented by Dr. Yannick Le Mer (Fondation Ophtalmologique A. de Rothschild, Paris – France), principal investigator of the feasibility trial in France.

The study investigators and medical advisory board members reviewed the safety data from the five consecutive PRIMA implantation surgeries, as well as patients' performance during the first months of the rehabilitation process. The latest dataset demonstrated the procedures required for safe implantation of the PRIMA, and successful activation of the central retina, which enabled first implanted patients to identify various visual patterns, including bars, letters and numbers.

**Dr. Yannick Le Mer concluded:** *“The wireless photovoltaic chip PRIMA could be safely implanted under the atrophic macula without post-operative decrease in residual peripheral vision in all five patients who lost their central vision due to Dry-AMD. The PRIMA chip elicited light perception in all patients. The rehabilitation program helps them improve the quality of visual perception. The study continues, and we are confident in successfully demonstrating positive feasibility study results.”*

The rehabilitation and assessment of the prosthetic vision continues, and the full set of 6-month interim results of the French feasibility study<sup>2</sup> is expected to be completed by the end of 2018. This will enable the design of the protocol for a larger multi-central European pivotal study, required for the CE-mark, to commence early in 2019.

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<sup>1</sup> Subretinal implantations of PRIMA wireless photovoltaic chip, a new surgical technique for atrophic dry age-related macular degeneration: Technical feasibility and early results

<sup>2</sup> Feasibility Study of Compensation for Blindness With the PRIMA System in Patients With Dry Age Related Macular Degeneration (PRIMA FS) <https://www.clinicaltrials.gov/ct2/show/NCT03333954>

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## ABOUT PRIMA

PRIMA is a new generation miniaturized and totally wireless sub-retinal implant. The 2x2 millimeters wide and 30 microns thick photovoltaic chip contains 378 electrodes. Implanted under the retina via a minimally invasive surgical procedure, it acts like an array of tiny solar panel powered by pulsed near infrared light projected from a miniature projector integrated in a pair of augmented reality glasses, along with a mini-camera. PRIMA is designed to restore some vision in patients blinded by retinal dystrophies – a very significant unmet medical need. The target population includes patients with atrophic dry Age-related Macular Degeneration (dry AMD), and also Retinitis Pigmentosa (RP). In addition to a clinical trial with five atrophic dry-AMD patients in France, PRIMA is approved for five-patients study in USA.

## ABOUT AGE-RELATED MACULAR DEGENERATION (AMD)

Age-related macular degeneration<sup>3</sup> is the leading cause of severe vision loss and legal blindness in people over the age of 65 in North America and Europe, impacting an estimated 12 to 15 million people worldwide, and rapidly growing due to ageing population. There are two forms of advanced AMD: the wet form, affecting about ~20% of AMD patients, where treatment like anti-VEGF injections slows down the disease progression, and the dry form, representing ~80% of AMD, where there is currently no curative treatment available. More than 4 million patients are afflicted with advanced dry AMD In Europe and the United States. Patients suffering from this retinal disorder gradually lose central vision (responsible for high visual acuity, required for reading and face recognition) due to loss of photoreceptors.

## ABOUT PIXIUM VISION

Pixium Vision's mission is to create a world of bionic vision for those who have lost their sight, enabling them to regain partial visual perception and greater autonomy. Pixium Vision's bionic vision systems are associated with a surgical intervention and a rehabilitation period. Pixium Vision is in clinical stage with PRIMA, its sub-retinal miniature photovoltaic wireless implant system, designed for patients who have lost their sight due to outer retinal degeneration, initially for atrophic dry age-related macular degeneration (dry AMD). Pixium Vision collaborates closely with academic and research partners spanning across the prestigious Vision research institutions including Stanford University in California, Institut de la Vision in Paris, Moorfields Eye Hospital in London, and Institute of Ocular Microsurgery (IMO) in Barcelona. The company is EN ISO 13485 certified and qualifies as "Entreprise Innovante" by Bpifrance.

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<sup>3</sup> [http://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(17\)30393-5/fulltext](http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(17)30393-5/fulltext)

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Pixium Vision is listed on Euronext Paris (Compartment C). Pixium Vision shares are eligible for the French tax incentivized PEA-PME and FCPI investment vehicles.

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