



Pixium Vision achieves successful activation of its photovoltaic PRIMA implant in all five study patients with Dry Age-related Macular Degeneration

Paris, France. August 30, 2018 – 7.00 AM 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, today announced a significant milestone in the development of PRIMA, its novel miniature wireless photovoltaic sub-retinal implant. The PRIMA device has been successfully activated in all five implanted patients with severe vision loss from atrophic dry Age-related Macular Degeneration (AMD).

The French feasibility study¹ with PRIMA is a 36-month, 5-patient clinical study, designed to evaluate the safety and function of the wireless photovoltaic sub-retinal PRIMA chip in eliciting visual light perception, with an interim 6-month analysis enabling preparation for our pivotal clinical study in the EU.

Following successful activations, all five consecutive patients in the French feasibility study reported perception of useful light patterns in areas where previously there was no remaining light perception. The training and rehabilitation follow-up (ranging two to nine months as end of August) enhances the patient's ability to learn to interpret their new artificial central macular perception. In addition, the success of the five consecutive implantations demonstrated the feasibility and the tolerability of the minimally invasive surgical technique as well as the stability of the implant.

The surgical procedure along with preliminary clinical observations from the first in Human implantation of PRIMA feasibility study will be presented during upcoming international congresses of Ophthalmology, EURETINA in September and EVER in October in Europe, and the annual congress of the American Academy of Ophthalmology (AAO) in October in Chicago, USA.

The full set of 6-month interim results of the French feasibility study are expected by the end of 2018 as planned. This will enable the design of the protocol for the larger multi-centric European pivotal study, which is required for the CE-mark, to commence in 2019.

In the United States, the first implantations of PRIMA are expected to be completed in the coming weeks at the University of Pittsburgh Medical Center (UPMC) in Pennsylvania, the single study center for the US feasibility study²: PRIMA FS-US.

Khalid Ishaque, Chief Executive Officer of Pixium Vision, stated: *"The successful consecutive activations of PRIMA in all five implanted study patients, combined with the preliminary clinical results and progress with the first implanted patients, are very encouraging for the clinical development of PRIMA. We look forward to reporting on the continued progress of the feasibility study, including the interim six-months combined follow-up data for the five patients, and the next phases of clinical development of PRIMA in Europe and in the United States."*

¹ 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>

² Feasibility Study of Compensation for Blindness with the PRIMA System in Patients with Atrophic Dry Age-Related Macular Degeneration (PRIMA-FS-US) <https://clinicaltrials.gov/ct2/show/NCT03392324>

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ABOUT PRIMA

PRIMA is a new generation miniaturized and totally wireless sub-retinal implant. The PRIMA implant is a micro photovoltaic chip of 2x2 millimeters wide and 30 microns thick, equipped with 378 electrodes. Implanted under the retina via a minimal invasive surgical procedure, it acts like a tiny solar panel that is powered by pulsed near infrared light through a miniaturized projector integrated in a pair of augmented reality-like glasses, along with a mini-camera, worn by the implanted subject. PRIMA is designed to compensate for severe vision loss from retinal dystrophies, initially atrophic dry Age-related Macular Degeneration (dry AMD), a significant unmet medical need with currently no curative therapeutic solution, and at later stage also Retinitis Pigmentosa (RP).

ABOUT AGE-RELATED MACULAR DEGENERATION (AMD)

Age-related macular degeneration³ 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 which is continuously growing due to ageing population. There are two forms of AMD, the wet form, representing ~20% of AMD, where treatment like anti-VEGF injections is available slow 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 start by losing their central vision (responsible for visual precision and details, for example, required for reading and face recognition) and progressively become blind.

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 as well as a rehabilitation period. Following the CE mark for its first bionic retinal implant systems, IRIS®II, Pixium Vision is now conducting clinical studies with PRIMA, its new generation sub-retinal miniaturized photovoltaic wireless implant system, 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 the Institut de la Vision in Paris, Stanford University in California, 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" par Bpifrance.

³ [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.

Pixium Vision is included in the Euronext CAC All Shares index

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Pixium Vision provides this press release as of the aforementioned date and does not commit to update forward looking statements contained herein, whether as a result of new information, future events or otherwise.

For a description of risks and uncertainties which could lead to discrepancies between actual results, financial condition, performance or achievements and those contained in the forward-looking statements, please refer to Chapter 4 "Risk Factors" of the company's Registration Document filed with the AMF under number R16-033 on April 28, 2016 which can be found on the websites of the AMF - AMF (www.amf-france.org) and of Pixium Vision (www.pixium-vision.com).

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