



## **Pixium Vision completes implantation of PRIMA in five patients with atrophic dry-AMD as expected for the feasibility clinical trial in France**

**Paris, France. July 10, 2018** – 7.00 AM CEST - Pixium Vision (FR0011950641 - PIX), a company developing innovative bionic vision systems to enable patients who have lost their sight to lead more independent lives, announced the fifth implantation of PRIMA, its novel miniature wireless photovoltaic sub-retinal implant, in patients with severe vision loss from atrophic dry Age-related Macular Degeneration (AMD). This final implantation completed the recruitment in the feasibility study cohort in France.

**PRIMA was also successfully activated in the fourth consecutive patient in the study. The patient with the fifth and final implant will have his device activated in the coming weeks as per the protocol.**

Following activation of previously implanted devices, the patients were able to perceive light patterns in areas where previously there was no remaining light perception. Rehabilitation as per protocol enables them to learn to interpret their new artificial central macular perception. The full set of 6-month interim results in the French feasibility study are expected to be available by end 2018 as planned. The interim 6-month follow-up results will enable Pixium Vision to prepare the protocol for the larger multi-centric European pivotal study phase, to obtain CE-mark.

In the United States, recruitment for the 5-patients single-center feasibility study<sup>1</sup> PRIMA-FS-US is fully active at the University of Pittsburgh Medical Center (UPMC) in Pennsylvania. Study candidates continue to be screened and the first implantations are expected during the third quarter 2018.

**Khalid Ishaque, Chief Executive Officer of Pixium Vision**, stated: *“Together with our clinical partners and their patients, we achieved a key milestone with the successful implant of the first five implantations of the PRIMA chip in the French feasibility study. The four successful activations of PRIMA to-date, with realization of light perception from the atrophic central macular zone of these dry-AMD patients, where no prior visual sensitivity had remained, provides feasibility evidence and strengthens confidence in pursuit toward the next phase of the European clinical development. In parallel, the US feasibility study recently initiated is actively recruiting patients and we look forward to report on the progress of the first implantations. In all, the clinical progress and experience to-date strengthens the confidence for PRIMA as a potential novel therapeutic option to compensate for blindness from retinal degeneration.”*

The French feasibility study<sup>2</sup> 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 to prepare for the pivotal clinical study in EU.

<sup>1</sup> 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>

<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 PRIMA implant is a micro photovoltaic chip of 2x2 millimeters and 30 microns thick, equipped with 378 electrodes. Implanted under the retina via a less 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 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 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.

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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.

Pixium Vision is included in the Euronext CAC All Shares index

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*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](http://www.amf-france.org)) and of Pixium Vision ([www.pixium-vision.com](http://www.pixium-vision.com)).*

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