



Pixium Vision announces its wireless PRIMA chip successfully met the interim study endpoints for dry Age-related Macular Degeneration

- *Implant is well tolerated while preserving residual peripheral visual acuity*
- *All subjects report light perception in their central visual field*
- *Majority of patients identifying complex patterns, letters or letter sequences*
- *Interim positive data enables to prepare the European multi Centre pivotal study*

Paris, France. January 8, 2019 – 7.00 AM CET - 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, announces its subretinal PRIMA system met the endpoints of the feasibility study¹, at interim 6 months follow-up after implantation and rehabilitation for patients with advanced dry Age-related Macular Degeneration (AMD).

Khalid Ishaque, Chief Executive Officer Pixium Vision, stated: *"We are very pleased with the remarkable results being achieved with PRIMA system with dry AMD patients. These results exceeded our initial expectations. For patients who had completely lost their central vision, PRIMA enabled majority of them to begin to correctly identify patterns and letters. We expect these remarkable first results to attract also eligible candidates for the PRIMA feasibility study² recruiting in the USA. Following this successfully significant milestone, we look forward to the pivotal clinical phase in Europe and subsequent CE Mark for PRIMA."*

The interim clinical results at 6 months with PRIMA, a wireless sub-retinal photovoltaic microchip, in patients with advanced dry-AMD, show:

- **PRIMA can be safely implanted under the atrophic macula while preserving the residual natural peripheral visual acuity**, measured under standardized conditions³.

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>

³ Standard vision tests used via ETDRS

- **Successful elicitation of light perception in the central retinal area in all subjects who had no remaining central visual activity**, validated by standardized clinical vision measures and tests⁴.
- **The implant is well tolerated, with no device-related serious adverse events**. Implant does not move after natural retina healing and remains stable in all patients.
- **Identification of patterns, numbers, or letters**, in a majority of the patients. The speed and accuracy of identifications improved continuously during the rehabilitation phase.
- **Central prosthetic visual acuity**⁵, measured up to 20/460 (LogMAR 1.37) within the former scotoma with no remaining natural central vision. **The achieved prosthetic visual acuity to date is the best among those published from current visual prosthetic technologies**.

Pixium Vision is preparing the larger European multicenter pivotal study required for the CE-mark.

Next event: 2018 Annual Results and Cash position – February 8th, 2019

⁴ Standard vision tests used via microperimetry and Octopus visual field test

⁵ Based on LandoltC visual acuity test

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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 into augmented reality glasses, along with a mini-camera. PRIMA is designed to restore sight 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 a similar five-patients study in USA.

ABOUT AGE-RELATED MACULAR DEGENERATION (AMD)

Age-related macular degeneration is the leading cause of severe vision loss and legal blindness in people over the age of 65 in North America and Europe. The global impact is significant with current projected estimates¹ for people living with AMD of around 196 million people worldwide and expected rapid growth due to ageing population. Around 1000 new patients are diagnosed everyday just in Europe and USA. There are two forms of advanced AMD: the wet form, where treatment like anti-VEGF injections slows down the disease progression, and the dry form that is most frequent, where there is currently no curative treatment available. More than 5 million patients are afflicted with advanced dry AMD, also referred to as Geographic Atrophy. Patients suffering from this retinal dystrophy gradually lose their central vision (responsible for high visual acuity, e.g. 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, Institute of Ocular Microsurgery (IMO) in Barcelona, and UPMC in Pittsburgh, PA. The company is EN ISO 13485 certified and qualifies as "Entreprise Innovante" by Bpifrance.

¹ Wong, W. L., Su, X., Li, X., Cheung, C. M. G., Klein, R., Cheng, C. Y., & Wong, T. Y. (2014). Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. *The Lancet Global Health*, 2(2), e106-e116 ([https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(13\)70145-1/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(13)70145-1/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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