



## **Pixium Vision highlights conclusions of its KOL Meeting: Experts confirm PRIMA's promises and potential to treat dry-AMD**

- PRIMA, an unprecedented, innovative and evolutive “brain-machine” interface in ophthalmology
- PRIMA, bionic vision solution designed for advanced atrophic dry-AMD
- PRIMA clinical performance to date exceeded initial expectations in advanced dry-AMD
- Next phase of clinical development and regulatory confirmed

**Paris, France. March 7, 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, hosted its first Key Opinion Leaders (KOL) meeting on March 5, 2019 in Paris. KOL in retinal disease, age-related macular degeneration (AMD) and prosthetic vision discussed the latest results with Pixium Vision's wireless subretinal photovoltaic PRIMA system and its potential and position in the AMD treatment armamentarium.

**Professor Frank Holz**, University of Bonn (Germany) and President elect EURETINA society, explained the inescapable degeneration process in AMD and reaffirmed the major burden of the disease in a patient's daily life and the importance of offering a treatment option to the increasing elderly population. He reiterated the significant unmet medical need and the lack of proven treatment options for the advanced dry form of AMD or Geographic Atrophy (GA) and the need for preventive and restorative solutions.

Professor Holz also welcomed the potential major benefit of PRIMA bionic vision system for treating dry-AMD when photoreceptors have degenerated, with capabilities to restore a useful form of central vision.

**Professor Daniel Palanker**, Stanford University (USA), inventor of the wireless PRIMA microchip, shared the rationale and mechanism of action of the system designed, from the start, for patients with dry-AMD. This includes a minimally invasive surgical procedure to enable preservation of peripheral visual acuity.

Professor Palanker also described the evolutive potential of PRIMA system functioning as a brain-machine interface for severe vision loss and blindness through:

- The on-going improvements of computer vision-processing software, and other intelligent features that can be integrated to further improve the image resolution and overall combined natural and prosthetic visual perception;
- The scalable and evolutive profile of PRIMA microchip technology, enabling future significant increases in the number pixels per chip, via more advanced processes.

**Professor José Sahel**, Sorbonne-Université (France) and University of Pittsburgh (USA) presented the results from PRIMA feasibility study<sup>1</sup> in patients with advanced dry-AMD. After reporting that all implanted patients confirmed light perception with PRIMA from atrophic central retina that no longer had any light perception, he focused on the performance of the majority of patients progressing, after training and reeducation, to identify letters and sequences of letters with positive improvement in central visual acuity through Landolt-C measurement. He also pointed out the minimal invasive character of the surgical procedure enabling preservation of residual natural visual acuity, a point of significance in assessing the safety profile, based also on the low level of mostly non-serious and treatable transitory adverse events to date.

**Professor Sahel** took the opportunity to also comment on the separate ongoing feasibility study being conducted in the US and outlined certain differences from the study in France including differences in the medical management of dry-AMD patients in the US healthcare system. He confirmed ongoing recruitment of patients and expects the first implantations during the first half of 2019.

In concluding the KOL meeting, Pixium Vision reaffirmed its plan next to proceed to the European pivotal clinical study with PRIMA. This pivotal study is expected to begin by the end of the current fiscal year. This trial will be a major milestone in the clinical development of the PRIMA system in advanced atrophic dry-AMD and represents a next step in its path to commercialization.

The presentation and the video recording of the KOL meeting will be available via Pixium Vision website in the coming days.

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<sup>1</sup> 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>

## 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 estimates<sup>1</sup> 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, University hospital in Bonn, and UPMC in Pittsburgh, PA. The company is EN ISO 13485 certified and qualifies as "Entreprise Innovante" by Bpifrance.

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<sup>1</sup> 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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