



## **Pixium Vision announces the publication of peer-reviewed clinical data of the Prima System in Dry AMD in the *Journal of Neural Engineering***

- Distance between the implant and the target cells was stable over the long-term follow-up
- No significant thickness changes of the retina after an initial phase of minor thinning

**Paris, France, October 11, 2022** – 07:00 CET – Pixium Vision SA (Euronext Growth Paris - FR0011950641; Mnemo: ALPIX), a bioelectronics company that develops innovative bionic vision systems to enable patients who have lost their sight to live more independent lives, announces today the publication of a paper in the *Journal of Neural Engineering* outlining further data from its Prima System, a photovoltaic substitute of photoreceptors providing simultaneous use of the central prosthetic and peripheral natural vision, implanted in human patients with atrophic dry age-related macular degeneration (AMD) to partially restore their vision.

The peer-reviewed paper in the *Journal of Neural Engineering*, entitled "Long-term Observations of Macular Thickness after Subretinal Implantation of a Photovoltaic Electronic Prosthesis in Patients with Dry Age-related Macular Degeneration," authored by Mahiul MK Muqit, Yannick Le Mer, Frank Holz and José-Alain Sahel, outlines the changes in neurosensory macular structures associated with subretinal implantation in geographic atrophy secondary to AMD. It was important to assess the retinal changes with PRIMA implants since the success of retinal stimulation with micro-electrodes largely depends on the distance between the stimulation electrode (in the implant) and the target cells.

The Spectral-Domain Optical Coherence Tomography (SD-OCT) images of three patients with subretinal implantations enrolled in the French feasibility study were analyzed to [1] measure the retinal thickness, [2] measure the distance between the array and the inner nuclear layer (INL, the layer of the retina made up of a number of closely packed cells, including bipolar cells) and [3] evaluate any potential macular changes from the surgical trauma.

The analysis found that the surgical delivery of the photovoltaic subretinal implant led to a stable retinal thickness over 36 months with no adverse structural or functional events after causing minor retinal thickness changes that settle after three months.

*"We are very pleased to announce the publication of these peer-reviewed data in the well-respected Journal of Neural Engineering showing that the surgical implantation of the Prima System in patients suffering from dry AMD leads to a stable retinal thickness three months after implantation," said Lloyd Diamond, Chief Executive Officer of Pixium Vision. "The PRIMA implant's small size and wireless design enable minimally invasive surgery. Previously, the data from the French feasibility study already demonstrated that the Prima System is well tolerated. The data in this paper now further demonstrate the stability and minimal impact of the implant once in position. We are confidently looking forward to the read-out from our pivotal PRIMAvision study on the Prima System due at the end of next year and our planned submission for market approval in Europe shortly afterward."*

### **Key take-aways**

The key take-aways from the data published in the *Journal of Neural Engineering* are:

- No significant changes in the distance between the surface of the implant and the INL (the Inner Nuclear Layer, the layer of the retina made up of a number of closely packed cells, including bipolar cells) were detected
- Total retinal thickness above the implant decreased by a mean of 39  $\mu\text{m}$  during 3-months post-implantation, but no significant changes were observed after that, up to 36 months of the follow-up

- The observations support the hypothesis that the retina on the different areas on the implant are equally supplied with nutrition and oxygen

Pixium Vision's pivotal PRIMAvéra study, which aims to demonstrate the safety and benefits of the Prima System, is ongoing in Europe, with a read-out expected towards the end of 2023 and regulatory submission for market approval due soon after. In the US, a feasibility study is also ongoing.

The full peer-reviewed *Journal of Neural Engineering* paper is available online [here](#).

## About Pixium Vision

**Pixium Vision** is creating a world of bionic vision for those who have lost their sight, enabling them to regain visual perception and greater autonomy. Pixium Vision's bionic vision systems are associated with a surgical intervention and a rehabilitation period. Prima System sub-retinal miniature photovoltaic wireless implant is in clinical testing 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, including some of the most prestigious vision research institutions in the world, such as 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.

**Forward-Looking Statements.** This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward looking statements, please refer to the Risk Factors ("Facteurs de Risques") section of the Company's 2021 Half-Year Financial Report and other documents the Company files with the AMF, which is available on the AMF website ([www.amf-france.org](http://www.amf-france.org)) or on the Company's website.

For more information: <http://www.pixium-vision.com/fr>

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Pixium Vision is listed on Euronext Growth Paris.  
Euronext ticker: ALPIX - ISIN: FR0011950641

Pixium Vision shares are eligible for the French tax incentivized PEA-PME and FCPI investment vehicles.

Pixium Vision is included in the Euronext GROWTH ALLSHARE index

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