



Pixium Vision announces first patient successful implantation in Prima System pivotal trial PRIMavera

- Study is the last clinical step before seeking market approval in Europe in dry AMD
- Bionic vision Prima System has shown excellent results in improving vision

Paris, France, April 7, 2021 – 7.00 a.m. CEST – Pixium Vision SA (Euronext Growth Paris - FR0011950641), a bioelectronics company that develops innovative bionic vision systems to enable patients who have lost their sight to live more independent lives, announces the successful first implantation of a patient in the PRIMavera pivotal trial of its bionic vision Prima System for atrophic dry age-related macular degeneration (AMD).

The PRIMavera study was initiated in Q4 2020 and aims to confirm the safety and the benefits provided by the Prima System and is the last clinical step before seeking market approval in Europe.

“This first successful implantation in the PRIMavera pivotal trial is an important milestone for the Prima System and for patients suffering from dry AMD. The Prima System has shown very encouraging results so far and I am looking forward to seeing confirmation of these life changing effects in dry AMD,” said **Dr Yannick Le Mer, Deputy Head of Vitreo-retinal Unit at Fondation Adolphe de Rothschild Hospital in Paris and Coordinating Investigator of the study.**

The PRIMavera study design is based on the positive data generated in a French feasibility study, showing the ability of patients with dry AMD to improve in visual acuity with the Prima System. Patients had a significant improvement in vision, gaining on average a logMAR of 0.5 (corresponding to 5 lines improvement).

A total of 38 patients will be enrolled in PRIMavera, an open label, baseline-controlled, nonrandomized, multi-center, prospective, single-arm confirmatory trial. The primary efficacy endpoint is the proportion of subjects with an improvement of visual acuity of logMAR 0.2 or more from baseline to 12 month and the primary safety endpoint is the number and severity of device and procedure related serious adverse events at 12 months follow-up. The study will include three years of follow-up, with assessment of the primary endpoints at 12 months after implantation.

“Pixium Vision continues to deliver on its transition from a research organization to a commercial one. This first implantation makes us a step closer to getting our highly innovative and exciting Prima System on the market and to the patients who are in desperate need,” said **Lloyd Diamond, Chief Executive Officer of Pixium Vision.** *“The Prima System has demonstrated excellent results in improving vision which will correlate to their ability to undertake day-to-day tasks, and has the potential to make a significant difference in the quality of life of patients suffering from dry AMD, who currently have no treatment options.”*

In addition to the ongoing PRIMavera study, Pixium Vision expects to report 36-month data from the French feasibility study by end 2021 / beginning 2022, and continues clinical development in the US.

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 conducting clinical feasibility studies of its Prima system, its miniaturised wireless sub-retinal implant, in patients who have lost their sight due to retinal degeneration associated with the dry form of AgeRelated Macular Degeneration (AMD). Pixium Vision works closely with world-renown academic partners, such as 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, USA. The company is EN ISO 13485 certified. Pixium Vision has been qualified as an “Innovative Company” by Bpifrance.

For more information: <http://www.pixium-vision.com/fr>
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Pixium Vision is listed on Euronext Growth Paris.
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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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