



Pixium Vision gaining confidence in execution timeline of the PRIMAvera pivotal trial following first patient implantation in the UK

- Successful implantation of the first patient in the PRIMAvera study in the UK
- Follows successful implantations in France and Germany
- PRIMAvera read-out now expected around end-2023

Paris, France, December 8, 2021 – 07.00 CET– 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 today the successful implantation of the first patient in the UK in the PRIMAvera pivotal trial in atrophic dry age-related macular degeneration (dry-AMD).

This follows the approval of the PRIMAvera study by the UK's Medicines and Healthcare Products Regulatory Agency and the opening of the first UK PRIMAvera clinical site at the Moorfields Eye Hospital in London. The PRIMAvera study aims to confirm the safety as well as the benefits provided by the Prima System and is the last clinical step before seeking market approval in Europe. The study was initiated in Q4 2020 in France, and the first patient was implanted in March 2021. Pixium Vision has since established additional clinical sites, implanted its first patient in Germany, and also plans to expand to additional clinical sites in Spain, the Netherlands, and Italy throughout H1 2022.

*"We are very proud to be part of the expansion of the PRIMAvera pivotal trial, and we are keen to help bringing this innovative system giving bionic vision to patients in need," said **Dr. Mahi Muqit, Consultant Ophthalmologist and Cataract and Vitreoretinal Surgeon at Moorfields Eye Hospital.** "It was the first implantation of the Prima System in the UK and at Moorfields Eye Hospital, and I was pleased by the simplicity of the procedure, making me confident that after overcoming the small learning curve, retinal surgeons will feel comfortable conducting this procedure, which can be life-changing for patients. Now that the patient has been implanted, we look forward to observing the progress the patient will make over the coming months."*

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 visual acuity with the Prima System.

A total of 38 patients will be enrolled in the PRIMAvera study, an open-label, baseline-controlled, non-randomized, multi-center, prospective, single-arm pivotal 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 months, 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 an assessment of the primary endpoints at 12 months after implantation.

While the PRIMAvera trial was initially expected to read-out in late 2022, longer than expected competent authority approvals due to COVID-19 have led to delayed openings of clinical centres. However, with the implantation of patients initiated at 7 sites in France, 6 in Germany and now the UK, Pixium anticipates the recruitment to complete by the end of 2022 leading to a read-out of the PRIMAvera study around the end of 2023.

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.

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

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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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