



Pixium Vision announces implantation of first patient in Italy in Prima System European pivotal trial PRIMavera

- First patient treated at PRIMavera clinical site in Rome, Italy
- Follows successful implantations at clinical sites in France, Germany, the UK and the Netherlands
- PRIMavera on track to read-out around the end of 2023

Paris, France, September 13, 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 successful first implantation of a patient in Italy in the PRIMavera pivotal trial in atrophic dry age-related macular degeneration (dry AMD).

This follows the approval of the PRIMavera study by the Italian Ministry of Health and the opening of the first clinical site in Italy at the Complesso Ospedaliero San Giovanni Addolorata. The PRIMavera study 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. The study was initiated in Q4 2020 in France. Pixium Vision has since established additional clinical sites and implanted patients in Germany, the UK and the Netherlands.

"We are very pleased to have successfully implanted the first patient in Italy with the Prima System as part of the expanding PRIMavera pivotal study," said Prof. Andrea Cusumano, co-investigator of the PRIMavera study for Italy. "We have been following the development of the Prima System since its inception and we have seen the significant promise it shows for those suffering from dry AMD, a disease for which we struggle to provide acceptable solution and hope to patients and their families. PRIMA's small size and wireless design means the implantation is a straightforward procedure which can be completed with minimal surgery. We will move ahead now with further implantations and we look forward to adding our efforts to the clinical assessment of this innovative technology."

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 implanted 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.

The implantation of patients has been performed at five sites in France, four in Germany as well as the Moorfields Eye Hospital in the UK, the Rotterdam Eye Hospital in the Netherlands and Complesso Ospedaliero San Giovanni Addolorata in Italy. Pixium Vision anticipates recruitment will be completed 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.

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) or on the Company’s website.

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

Follow us on [@PixiumVision](https://twitter.com/PixiumVision); www.facebook.com/pixiumvision

Linked in www.linkedin.com/company/pixium-vision



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

Contacts

Pixium Vision

Offer Nonhoff
Chief Financial Officer
investors@pixium-vision.com
+33 1 76 21 47 68

Media Relations

LifeSci Advisors
Sophie Baumont
sophie@lifesciadvisors.com
+33 6 27 74 74 49

Investor Relations

LifeSci Advisors
Guillaume van Renterghem
gvanrenterghem@lifesciadvisors.com
+41 76 735 01 31