

Pixium Vision announces successful implantation of first patient in the Netherlands in Prima System European pivotal trial PRIMAvera

- PRIMAvera clinical site opens at the Rotterdam Eye Hospital in the Netherlands
- Follows successful implantations at clinical sites in France, Germany and the UK
- New clinical sites to open in Spain and Italy
- PRIMAvera read-out expected around the end of 2023

Paris, France, July 26, 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 implantation of the first patient in the Netherlands in the PRIMAvera pivotal trial in atrophic dry age-related macular degeneration (dry AMD).

This follows approval of the PRIMAvera study by the Dutch Ministry of Health, Welfare and Sport and the opening of the first PRIMAvera clinical site in the Netherlands at the Rotterdam Eye Hospital. The PRIMAvera study aims to confirm the safety and clinical 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 where the first patient was implanted in March 2021. Pixium Vision has since established additional clinical sites and implanted patients in Germany as well as the UK and anticipates recruitment will be completed by the end of 2022 leading to a read-out of the PRIMAvera study primary endpoints around the end of 2023.

"The PRIMAvera study has been making impressive progress with the implantation of patients in new clinical sites across Europe and we are very pleased to be joining these efforts to help bring the benefits of the innovative Prima System to those suffering from dry AMD," said **Dr. Koen van Overdam, Consultant Ophthalmologist and Vitreoretinal Surgeon at the Rotterdam Eye Hospital.** "The potential of the technology and the relative ease with which the small wireless implant can be surgically placed under the macula offer a real chance for patients who lost vision due to dry AMD and we look forward to contributing further to the PRIMAvera study."

The PRIMAvera study design is based on the positive data generated in the 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, nonrandomized, 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 after 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.

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: Attp://www.pixium-vision.com/fr Follow us on <u>Marked in www.linkedin.com/company/pixium-vision</u>



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

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