PRESS RELEASE

# Pixium Vision announces completion of implantations in the European pivotal trial PRIMAvera and confirms target read-out around the end of 2023 and regulatory submission in Europe in H1 2024

- 38 patients have been implanted with Prima System in pivotal trial
- Data will also play an important supporting role in US regulatory submission

**Paris, France, December 15, 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 completion of implantations in all the patients enrolled in the PRIMAvera European pivotal trial in atrophic dry age-related macular degeneration (dry AMD), also known as Geographic Atrophy.

A total of 38 patients have been implanted with the Prima System in the PRIMAvera study (NCT04676854), an open-label, baseline-controlled, non-randomized, multi-center, prospective, single-arm pivotal trial. The 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 is being conducted in leading clinical centers in France, Germany, the UK, the Netherlands, and Italy. A read-out of the PRIMAvera study's primary endpoints is expected around the end of 2023.

*"This is an important milestone in the clinical development of our innovative Prima System, and we are very pleased to have reached it successfully,"* said **Lloyd Diamond, Chief Executive Officer of Pixium Vision.** *"I'd like to thank all the physicians and patients involved in the PRIMAvera study as well as the whole Pixium team for their hard work in contributing to this significant achievement. We are now looking ahead to next year's read-out on the primary endpoints. From there we expect to be able to start discussions with the European regulator in preparation for bringing this cutting-edge technology to market for the benefit of those suffering from the loss of their sight due to dry AMD. Along with the US and French feasibility studies, we expect that the data from the PRIMAvera pivotal study will also play an important supporting role in the US regulatory submission."*

*"I am proud to be leading the PRIMAvera pivotal study and of the progress we have made in opening multiple clinical sites across Europe and completing dozens of successful implantations,"* said **Professor Frank Holz, Scientific Coordinator of the PRIMAvera study.** *"It is a testament to the skill of the surgical teams involved in the study and to the technological integrity of the Prima System that the implantations have proceeded in such an efficient and expeditious manner. We also saw better-than-expected recruitment demonstrating a strong interest among patients suffering from late-stage atrophic age-related macular degeneration in the PRIMA implant and the study as a whole. We are looking forward to next year's target read-out and to hopefully having the Prima System available to the many patients affected by dry AMD."*

*"The PRIMAvera pivotal study marks a major step forward in the treatment of atrophic dry AMD and it is very rewarding to see the Prima System progressing so well in a clinical setting,"* said **Professor José-Alain Sahel, M.D., University of Pittsburgh School of Medicine and a co-founder of Pixium Vision.** *"We have great confidence in the technology as Pixium has already demonstrated how the prosthetic central vision generated by the Prima System can be used simultaneously with patients' remaining peripheral vision, indicating the technology's potential to help improve the lives of those suffering from dry AMD, who currently have no other treatment options."*

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. The primary efficacy endpoint of the PRIMAvera study 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.

Pour plus d'informations: http://www.pixium-vision.com/fr
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