PRESS RELEASE

# Pixium Vision announces FDA Breakthrough Device Designation for the Prima System in Dry AMD

- Pixium Vision to receive interactive communication with FDA through premarket review phase of Prima System and potential prioritized regulatory review
- Breakthrough Device Designation aims to expedite development of medical devices that can treat or diagnose life-threatening or debilitating conditions
- PRIMAvera European pivotal trial in dry AMD fully recruited and on track to report primary endpoints around the end of 2023
- Streamlined reimbursement options available upon approval in the United-States

**Paris, France, March 31, 2023** – 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 U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to the company's Prima System, a photovoltaic substitute of photoreceptors providing simultaneous use of the central prosthetic and peripheral natural vision implanted in human patients with atrophic dry age-related macular degeneration (AMD) to partially restore their vision.

The Breakthrough Device Designation aims to supply patients and healthcare providers with timely access to new medical devices that offer more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions by speeding up their development, assessment and review. To receive the designation, a device must also have either breakthrough technology, or no approved or cleared alternatives, or significant advantages over existing approved or cleared alternatives, or its availability must be in the best interest of patients.

Under the program, Pixium Vision will have the opportunity to interact with the FDA's experts during the premarket review phase of the Prima System to identify areas of agreement in a timely way and could also receive prioritized review of the regulatory submission.

*"To receive this Breakthrough Device Designation and have the FDA recognize the therapeutic potential of our Prima System is a significant achievement for Pixium Vision, especially as only a small proportion of devices awarded the designation are intended to treat ophthalmologic conditions[1],"* said **Lloyd Diamond, Chief Executive Officer of Pixium Vision.** *"Our Prima System is making great progress in the clinic with a read-out on the primary endpoints due toward the end of this year. This designation not only helps us to expedite the development of the Prima System but also affords us the opportunity of working closely with the FDA in refining the Prima System for its US regulatory submission. In addition, after receiving market authorization, there are outpatient and inpatient reimbursement pathways that are more readily accessible as a result of receiving Breakthrough Device Designation."*

In December 2022, Pixium Vision announced the completion of implantations in the European pivotal trial PRIMAvera and confirmed a read-out of the study's primary endpoints around the end of 2023, with a regulatory submission in Europe in H1 2024.

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.

[1] https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s2

## 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; www.facebook.com/pixiumvision
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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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