



## Pixium Vision announces reaching its enrollment target in the European pivotal trial PRIMavera and implantations planned to be completed by end 2022

- The target number of 38 patients have been enrolled at clinical sites in France, Germany, the UK, the Netherlands, and Italy
- Waiting list for additional patients initiated to replace potential pre-implantation drop-outs and ineligibility
- Implantations due to be completed by the end of 2022; PRIMavera read-out expected around the end of 2023

**Paris, France, September 19, 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 patient enrollment in the PRIMavera pivotal trial in atrophic dry age-related macular degeneration (dry AMD), also known as Geographic Atrophy.

A total of 38 patients have been enrolled in the PRIMavera study (NCT04676854), an open-label, baseline-controlled, non-randomized, multi-center, prospective single-arm pivotal trial. A waiting list for additional patients has also been established to replace any of the current 38 patients who could prove ineligible for implantation or drop out before implantation takes place. 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 enrolled in December 2020. Pixium Vision has since established additional clinical sites and implanted patients in France, Germany, the UK, the Netherlands, and Italy. Implantations are due to be completed by the end of 2022, and a read-out of the PRIMavera study's primary endpoints is expected around the end of 2023.

*"We are very pleased to have reached the target patient number in our pivotal PRIMavera study, which has been making great progress since it was initiated in late 2020," said **Professor Frank Holz, the lead investigator for Germany and scientific coordinator of the PRIMavera study.** "We are excited to be advancing this innovative technology towards the market where patients suffering from dry AMD could benefit. We are looking forward to completing the implantations by the end of the year and announcing the study's read-out around the end of 2023."*

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](http://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](https://www.facebook.com/pixiumvision)

[Linkedin www.linkedin.com/company/pixium-vision](https://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](mailto:investors@pixium-vision.com)  
+33 1 76 21 47 68

### Media Relations

**LifeSci Advisors**  
Sophie Baumont  
[sophie@lifesciadvisors.com](mailto:sophie@lifesciadvisors.com)  
+33 6 27 74 74 49

### Investor Relations

**LifeSci Advisors**  
Guillaume van Renterghem  
[gvanrenterghem@lifesciadvisors.com](mailto:gvanrenterghem@lifesciadvisors.com)  
+41 76 735 01 31