



## Pixium Vision announces implantation of first patient in Germany in Prima System European pivotal trial PRIMAvera

- Successful first implantation of a patient in the PRIMAvera study in Germany
- PRIMAvera clinical sites opening in five locations in Germany
- Additional clinical sites to open in additional European countries

**Paris, France, September 23, 2021** – 07.00 CET– Pixium Vision SA (Euronext Growth Paris - FR0011950641), a bioelectronics company that develops innovative bionic vision systems to enable patients who have lost their sight to live more independent lives, announces the successful first implantation of a patient in Germany in the PRIMAvera pivotal trial.

This follows approval of the PRIMAvera study by Germany's Federal Institute for Drugs and Medical Devices, which 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. PRIMAvera clinical sites have now opened in Bonn, Sulzbach, Hamburg, Munich and Ludwigshafen with one more in Tuebingen to follow. The PRIMAvera study was initiated in Q4 2020 and the first patient was implanted in March 2021.

*"We are pleased to initiate the patient treatment in Germany as part of the PRIMAvera pivotal trial, which is continuing to make good progress," said Prof. Frank Holz, the lead investigator for Germany and scientific coordinator of the study. "The bionic vision Prima System has demonstrated improved vision function and could potentially make a significant impact to patients' quality of life. We are looking forward to studying the Prima System further in the PRIMAvera trial and bringing it to more patients in need."*

*"I have followed the development of the PRIMA System for some time and am very proud to implant the first PRIMA device in Germany. I consider the Prima System to bring true innovation to patients and me and my team are keen to see the results of this pivotal trial" said Prof. Peter Szurman, Chief Physician at the Augenklinik in Sulzbach, Germany.*

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 in visual acuity with the Prima System.

A total of 38 patients will be enrolled in PRIMAvera, an open label, baseline-controlled, nonrandomized, multi-center, prospective, single-arm confirmatory 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 month 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 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.

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

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Pixium Vision is listed on Euronext Growth Paris.  
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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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