



Pixium Vision announces positive follow-up data from Prima System study in dry AMD

- *Prima System improves visual acuity of the implanted patients*
- *Prima System confirmed its safety and tolerance up to 24 months*
- *Pixium Vision pursues the design of pivotal clinical trial PRIMAvEra*

Paris, March 31st 2020 – 6:00 PM CEST– Pixium Vision (FR0011950641 - ALPIX), a bioelectronics company that develops innovative bionic vision systems to enable patients who have lost their sight to live more independently, today announces positive follow-up data from the French feasibility trial of the Prima System in patients with dry age-related macular degeneration (AMD).

The follow-up from 18 to 24 months after implantation showed that the Prima System sustainably elicited light perception in all four dry AMD patients¹ with favourable safety profile. Moreover, the second-generation transparent glasses, enabling to combine natural peripheral vision and prosthetic vision, greatly benefited patients and their visual acuity which improved by a minimum of logMAR 0.3 (or 3 lines) and up to logMAR 0.7 (or 7 lines). It complements and builds on the previously announced [positive 12-month clinical data](#), and reinforces the clinical feasibility of the Prima System in good safety conditions and the functionality of the new transparent glasses.

“The Prima System has demonstrated excellent results in improvement of visual acuity in this study and which have not been previously demonstrated in this patient population. A 3-line improvement can mean the difference between recognizing or not recognizing the letters on a street sign, and so these data reinforce the potential to make a significant difference to the lives of patients” said Dr Yannick le Mer, the surgeon who implanted the Prima System patients in the study, who is Head of the Vitreo-retinal Unit at Fondation Adolphe de Rothschild Hospital in Paris and a scientific advisor to Pixium Vision.

“We are absolutely delighted with these very impressive clinical data which pave the way to progress the Prima System into the PRIMAvEra pivotal trial, required for potential marketing approval. We now have compelling additional evidence that Prima System can improve dry AMD patients’ sight potentially offering them - and their care givers - greater independence in good safety conditions. This is made even more significant by the fact that dry AMD patients currently have no other treatment options,” said **Lloyd Diamond, Chief Executive Officer of Pixium Vision.**

Based on these positive data the Prima System will be tested in PRIMAvEra, the pivotal trial designed to provide the safety and efficacy data required for filing marketing authorization applications in the U.S., Europe and other parts of the world.

¹ One of the five patients originally recruited to the study did not complete it for reasons unrelated to Prima System or to the procedure.

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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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