



## Pixium Vision announces positive long-term follow-up scientific data on PRIMA implant from Prima System French feasibility study

- PRIMA implant is well tolerated and safe in patients 36 months after implantation
- Implant is highly stable with no lifetime deteriorations observed
- PRIMA can potentially provide meaningful visual acuity improvement

**Paris, France, 13.10.2021** – 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 positive long-term data from patients implanted with PRIMA, a state-of-the-art implantable chip. The data were presented at The Eye and The Chip – Virtual Event, held October 3-5, 2021.

Dr. Yannick Le Mer, Head of Vitreo-retinal Unit at Fondation Adolphe de Rothschild Hospital in Paris and Principal Investigator of the PRIMAvra pivotal study, commented: *"I was delighted to present such positive scientific data about PRIMA, our proprietary breakthrough sub-retinal wireless implant. PRIMA can be implanted easily without causing severe or untreatable complications. Furthermore, the implant is shown to be reliable in patients for over 36 months post implantation. These encouraging results position Pixium's PRIMA implant, and the whole Prima System, as a realistic potential solution for people who suffer from loss of central vision due to dry age-related macular degeneration (Dry AMD), a large patient population with no solutions to improve their low quality of life currently on the market."*

PRIMA, Pixium's proprietary subretinal implant for Atrophic Dry AMD, was shown in clinical trials to be easily and safely implanted in patients, thanks to the unique design of the implant itself and Pixium's proprietary delivery system used for implantations (Figure 1).

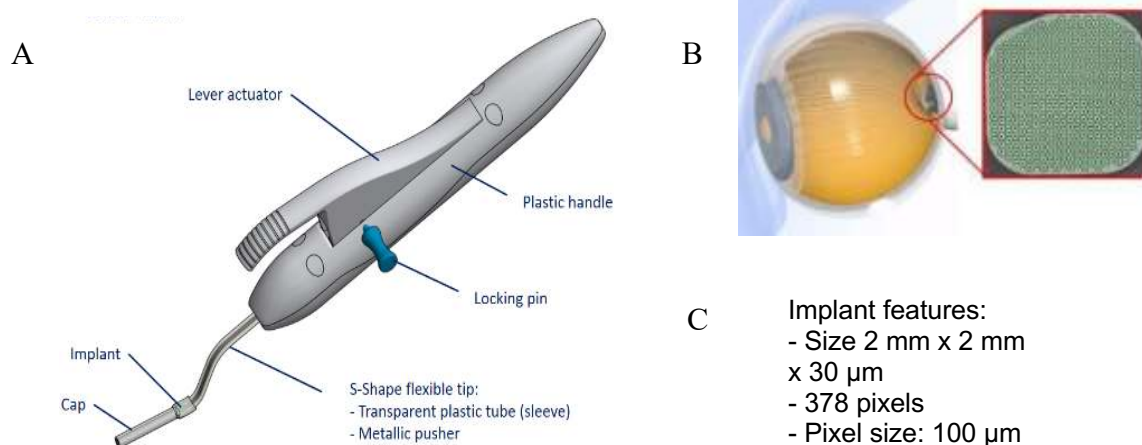


Figure 1: Implant and delivery system design. A: delivery system B: PRIMA implant and its location at the retina C: Implant features

In the French feasibility study, five patients were observed and followed for up to 36 months post implantation, demonstrating no implant lifetime failure. These observations are in line with in vitro reliability studies that showed the implants to be 100% reliable with pixels reliability of over 90%, for over 20 years.

Results from the feasibility study of compensation for blindness with the Prima System in patients with Dry AMD have shown:

- A significant improvement of up to logMAR 0.9 in visual acuity
- PRIMA implants are well tolerated and safe in the implanted subjects
- Integration of natural and artificial vision
- No decrease of residual natural visual acuity in any of the patients
- Unprecedented improvement in daily reading tasks demonstrating the feasibility of living with PRIMA

Following the successful results of the French feasibility study, the PRIMA implants and Prima System entered PRIMAvéra, a European pivotal study design. A total of 38 patients will be enrolled in PRIMAvéra, 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 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 assessment of the primary endpoints at 12 months after implantation.

The French feasibility study ([NCT03333954](#)) enrolled 5 patients who were implanted with the PRIMA sub-retinal implant in one eye. Following a successful rehabilitation process, implanted patients have shown significant improvement in visual acuity.

## 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.  
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