



World Premiere

Pixium Vision implants *IRIS® II*, first epi-retinal implant with 150 electrodes

A major step forward in bionic vision for patients with retinitis pigmentosa

Paris, France - February 24, 2016 – Pixium Vision (FR0011950641 – PIX) a company developing innovative bionic vision systems to allow patients who have lost their sight to lead more independent lives, announces today the first implant and successful activation of *IRIS® II*, the only epi-retinal implant with 150 electrodes, intended for patients who have lost sight as a result of retinitis pigmentosa (RP).

The first human implant of *IRIS® II* was successfully performed in January, by **Professor Michel Weber, Head of Ophthalmology at the University Hospital of Nantes, France**. This is part of Pixium Vision's ongoing clinical trial to assess the safety and performance of *IRIS® II* as a treatment to compensate for blindness by providing a form of bionic vision and enabling greater autonomy for patients.

Professor Weber commented: *"This first implant was successfully completed for the 58 year old retinitis pigmentosa patient. With the implant design and its smart retinal fixation, the procedure is close to the surgical techniques familiar to the retinal surgeons."* **Pr. Weber** added: *"After many years in darkness, the patient was activated and reported first perception of light. Per clinical protocol, the patient will now enter training to learn how to interpret the light signals."*

The implant activation and first light perception provide tangible evidence of visual perception. It precedes the normal rehabilitation process where, per protocol, the patient learns to interpret the bionic vision.

Dr Yannick Le Mer, a pioneer in retinal implant surgery at the *Fondation Ophtalmologique Rothschild* in Paris (a centre of excellence for ophthalmic surgery participating in the study with *Hôpital des Quinze-Vingts*) added: *"The new *IRIS® II* implant represents a major step forward for patients with retinitis pigmentosa: the intervention is relatively quick thanks to the design of the implant and it is now equipped with 150 electrodes, close to three time more than currently available. Epi-retinal approach is currently the less invasive and most optimal solution to allow retinitis pigmentosa patients to emerge from darkness."*

Khalid Ishaque, CEO of Pixium Vision, said: *"The first implant and activation of *IRIS® II*, with its innovative features, is an exciting and major advance in the field of bionic vision development, interfacing the eye and the brain. Pixium Vision is dedicated to conceive, develop and bring meaningful bionic vision innovations to surgeons, enabling them to treat patients who have lost sight."*

Up to 10 patients will be included in the ongoing clinical trial in several specialized centres in Europe. In December 2015, Pixium Vision filed for CE mark. Subject to CE mark approval, *IRIS® II* should be commercially available around mid-2016.

IRIS® II incorporates innovative characteristics:

- A **smart bio-inspired camera** that is intended to function like the human eye: the sensor does not take a sequence of video frames, essentially composed of redundant information, but continuously captures the changes in a visual scene with its time independent pixels;

- An **epi-retinal implant with 150 electrodes**, almost three times more electrodes than available today;
- An **explantable design**: the electrode array is secured on the retinal surface by a patented support system that allows explantation, minimizing risk of retinal damage and permitting potential for upgrade to newer therapy options.

Earlier in the year, Pixium Vision also announced promising pre-clinical safety data¹ for its next generation PRIMA implant, a miniaturized wireless sub-retinal implant in preparation for the first in human feasibility study later this year.

About the IRIS® II clinical study:

Study title: "Compensation for Blindness with the Intelligent Retinal Implant System (IRIS V2) in Patients With Retinal Dystrophy (IRIS 2)"

<https://clinicaltrials.gov/ct2/show/NCT02670980?term=Compensation+for+Blindness+with+the+Intelligent+Retinal+Implant+System+%28IRIS+V2%29+in+Patients+With+Retinal+Dystrophy+%28IRIS+2%29&rank=1>

The IRIS® II clinical trial is a multi-centric, open label, non-randomized prospective European study to assess safety and performance of the IRIS® II bionic vision system as treatment to compensate for blindness, providing a form of perception for blind persons and enabling them greater autonomy and quality of living.

Up to 10 patients suffering from retinitis pigmentosa, Cone-Rod dystrophy, choroideremia will be included and followed for a minimum of 18 months and an additional 18 months, subject to patient agreement.

Clinical trials are currently underway in 7 centers below. Additional centers are being opened in United Kingdom and Spain.

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¹ Retinal safety of near infrared radiation in photovoltaic restoration of sight: *Biomedical Optics Express* Vol. 7, Issue 1, pp. 13-21 (2016) •doi: 10.1364/BOE.7.000013 <https://www.osapublishing.org/boe/abstract.cfm?uri=boe-7-1-13&origin=search>

About Pixium Vision (www.pixium-vision.com)

Pixium Vision's Mission is to create a world of bionic vision for those who have lost their sight enabling them to regain partial perception and greater autonomy and improved quality of daily living. Pixium Vision is the only company today developing in parallel 2 innovative bionic retinal implant systems, which incorporate active implantable prostheses intended to treat and compensate for blindness resulting from the degeneration of retinal photoreceptor cells. The Company harnesses the rapid advances in neuroscience, neuromorphic visual processing, microelectronics / nanoelectronics, optoelectronics, neurobiology and intelligent software algorithms. These bionic systems are intended for blind people whose optic nerve remains functional. Pixium Vision's bionic vision systems are associated with a surgical intervention as well as a rehabilitation period.

European Clinical trials are currently underway with IRIS®, the company's first bionic vision system. Patients have tolerated their implants well so far and improvements in visual perception have been observed. Pixium Vision has filed IRIS's CE mark dossier at the end of 2015 and expects CE mark approval by mid-2016.

Pixium Vision is, in parallel, also developing PRIMA, a sub retinal miniaturized wireless implant platform currently in preclinical studies. The Company plans to begin clinical trials with PRIMA in Europe in 2016.

The company is EN ISO 13485 certified.

Pixium Vision maintains close collaborations with academic and research partnerships spanning across the prestigious Vision Institute in Paris, the Hansen Experimental Physics Laboratory at Stanford University, as well as several global scientific, medical, clinical, and technology experts, resulting also in strong intellectual property portfolio.



Pixium Vision is listed on Euronext (Compartiment C) in Paris.
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IRIS® is a trademark of Pixium-Vision SA

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Pixium Vision provides this press release as of the aforementioned date and does not commit to update forward looking statements contained herein, whether as a result of new information, future events or otherwise.

For a description of risks and uncertainties which could lead to discrepancies between actual results, financial condition, performance or achievements and those contained in the forward-looking statements, please refer to Chapter 4 "Risk Factors" of the company's Registration Document filed with the AMF under number R15-069 on September 23, 2015 which can be found on the websites of the AMF - AMF (www.amf-france.org) and of Pixium Vision (www.pixium-vision.com).