



## **Pixium Vision announces the first successful implantation and activation of IRIS<sup>®</sup> II, 150 electrode bionic vision system, in the UK**

*World renowned Moorfields Eye Hospital in London implanted the first patient with IRIS<sup>®</sup> II, a bionic vision system equipped with a bio-inspired camera and a 150 electrode epi-retinal implant that is designed to be explantable.*

**Paris, France, London, UK, November 7th, 2016** – Pixium Vision (FR0011950641 – PIX, “Pixium”), a company developing innovative bionic vision systems with the intention to allow patients who have lost their sight to lead more independent lives, announces the first successful implantation and activation of IRIS<sup>®</sup> II in the UK. This epi-retinal implant with 150 electrodes is intended for patients who have lost sight as a result of retinitis pigmentosa (RP).

The first implant of IRIS<sup>®</sup> II in UK was successfully performed in September, by **Dr. Mahi Muqit, PhD FRCOphth, Consultant Ophthalmologist and Vitreoretinal Surgeon at Moorfields Eye Hospital, study Principal Investigator in UK**. This is part of Pixium Vision’s ongoing multi-centre clinical trial to assess the performance of IRIS<sup>®</sup> II as a treatment to compensate for blindness by the intended provision of a form of bionic vision and greater autonomy for patients. Moorfields Eye Hospital NHS Foundation Trust is one of the clinical centres of excellence participating in the multicentre European study across France, Germany and Austria, UK and Spain. Moorfields Eye Hospital is one of the oldest and largest centre for ophthalmic treatment, teaching and research in Europe.

**Dr. Muqit commented:** *“This first IRIS<sup>®</sup> II retinal implant in the UK was successfully completed for the 73 year old retinitis pigmentosa patient. The 150 electrode implant with its explantable design, may become an innovative option for the retinal surgeons. Participation in this European clinical trial allows us to evaluate the new system.”* **Dr. Muqit added:** *“The patient’s system was activated and he reported first perception of light. Per clinical protocol, the patient will now enter training and re-adaptation to learn how to interpret the new light signals.”*

The implant activation and first light perception illustrates that some visual perception may become available. It precedes the normal re-adaptation and re-education process where, per protocol, the patient enters a learning process to interpret the new form of bionic vision which is different to the natural form of vision.

**Khalid Ishaque, CEO of Pixium, added:** *“The first IRIS<sup>®</sup> II implant in UK at the prestigious Moorfields hospital, is part of the company’s strategy to continue to expand its presence across centres of excellence in Europe. Pixium Vision is dedicated to conceive, develop and bring meaningful bionic vision innovations to surgeons, which shall enable them to treat patients who have lost sight to retinal dystrophies.”*

In parallel, the company continues to progress with development of its second system, PRIMA, a wireless sub-retinal implant, with a less invasive design than IRIS<sup>®</sup> and which is intended to be suitable, particularly, for AMD. First preclinical studies enabled the submission to regulatory bodies for a feasibility study for Age-related Macular Degeneration (AMD).

## About Moorfields Eye Hospital

Moorfields Eye Hospital NHS Foundation Trust is considered as one of the world's leading eye hospitals, providing expertise in clinical care, research and education. It has provided excellence in eye care for more than 200 years and continues to be at the forefront of new breakthroughs and developments. Moorfields Eye Hospital NHS Foundation Trust is an integral part of one of the UK's first academic health science centres, UCL Partners, and now it is part of one of the first science health networks. It was one of the first organisations to become an NHS foundation trust in 2004. For further information, please visit [www.moorfields.nhs.uk](http://www.moorfields.nhs.uk).

## About IRIS®II

IRIS®II is a bionic vision system equipped with a bio-inspired camera and a 150 electrodes epi-retinal implant with a proprietary design intended to be explantable and eventually upgradable for patients who have lost sight due to Retinitis Pigmentosa (RP).

### - Clinical studies

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

<https://www.clinicaltrials.gov> Ref: NCT02670980.

During this study, the performance and safety of IRIS®II is being evaluated. There is not yet sufficient data available for the IRIS®II system to compare it with other devices and therapies, and no claims are made as to performance, safety or even superiority of IRIS®II or its features.

The IRIS®II clinical trial, initiated in January 2016, is a multi-centric, open label, non-randomized prospective European study to assess effectiveness of the IRIS®II bionic vision system as treatment intended to compensate for blindness, by eventually 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, Usher Syndrome, Cone-Rod dystrophy, choroideremia will be included and followed for a minimum of 18 months, with additional 18 months follow-up, subject to patient consent. The company has implanted four patients thus far and expects the recruitment to be completed by YE 2016. Interim data from the trial should further assist reimbursement applications in EU territories.

Pixium Vision recently received approval from the Spanish Regulatory Authorities in September 2016 for initiating the clinical trial with the IRIS®II. Barcelona's Institute of Ocular Microsurgery (IMO) has joined other prestigious European study sites, including centres from France, Austria, Germany, and the UK (Moorfields Eye Hospital in London).

<http://www.pixium-vision.com/en/clinical-trial/participating-centers>

### - CE Mark, reimbursement, and start of commercial and market development activities

The Company received CE mark for IRIS®II at the end of July 2016, enabling Pixium to launch its commercial activities subject to reimbursement availabilities.

CE mark approval for IRIS®II system enables the company to file for national reimbursements. The Company is working initially with public reimbursement authorities for innovative technologies for medical devices in France (under "Forfait Innovation") and in Germany (with NUB). The Company expects to obtain IRIS®II reimbursement prior to the completion of the ongoing study.

## About PRIMA

Pixium Vision recently completed preclinical phases including thermal and electrical safety studies on the safety thresholds requirements for the eye. Clinical studies are necessary to evaluate PRIMA's performance and safety.

The Company has submitted to the regulatory authorities a protocol for first-in-human feasibility study for AMD. Pixium expects, that with an approval by YE 2016, to potentially complete enrolment by mid-2017. The Company is also scheduling discussion with the FDA to define US clinical study timeline.

The PRIMA device is being developed, in particular, for the much larger late-stage AMD market. For further information about the PRIMA technology please visit:

<http://www.pixium-vision.com/en/technology-1/prima-vision-restoration-system>

**About Pixium Vision** ( [www.pixium-vision.com](http://www.pixium-vision.com);  [@PixiumVision](https://twitter.com/PixiumVision);  [www.facebook.com/pixiumvision](https://www.facebook.com/pixiumvision))

Pixium Vision's Mission is to create a world of bionic vision for those who have lost their sight, enabling them to regain partial visual perception and greater autonomy. Pixium Vision's bionic vision systems are associated with a surgical intervention as well as a rehabilitation period. The Company aims to enable patients who have lost their sight to lead more independent lives.

The company obtained CE mark for IRIS®II, its first bionic system, in July 2016.

Pixium Vision is, in parallel, developing PRIMA, a sub-retinal miniaturized wireless photovoltaic implant platform for the Age-related Macular Degeneration (AMD) indication. The company recently completed the pre-clinical study phases and plans to initiate first-in-human trials in Europe by end 2016.

The company is EN ISO 13485 certified.

Pixium Vision collaborates closely with academic and research partners spanning across the prestigious Vision research institutions including the Institut de la Vision in Paris, the Hansen Experimental Physics Laboratory at Stanford University, and Moorfields Eye Hospital in London.



Pixium Vision is listed on Euronext (Compartment C) in Paris  
ISIN: FR0011950641; Mnemo: PIX  
IRIS® is a trademark of Pixium-Vision SA

Pixium Vision shares are eligible for the French tax incentivized PEA-PME and FCPI investment vehicles.



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*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 R16-033 on April 28, 2016 which can be found on the websites of the AMF - AMF ([www.amf-france.org](http://www.amf-france.org)) and of Pixium Vision ([www.pixium-vision.com](http://www.pixium-vision.com)).*