



## **Pixium Vision receives clinical trial approval from UK Regulatory Authority for 150 electrode IRIS® II bionic vision system**

*World renowned Moorfields Eye Hospital joins the clinical trial for IRIS® II, a bionic vision system equipped with a bio-inspired camera and a 150 electrode epi-retinal implant with an explantable design*

**Paris, France – May 31 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, today announced that it has received approval from the Medicines & Healthcare products Regulatory Agency (MHRA) in the UK to initiate a clinical trial for patients who have lost sight due to retinitis pigmentosa (RP) with the IRIS® II bionic vision system. This system being evaluated includes a mini bio-inspired camera and a 150 electrode epi-retinal implant with an explantable design.

Participation of Moorfields Eye Hospital NHS Foundation Trust broadens the clinical study centres of excellence in addition to sites across France, Germany and Austria. Moorfields Eye Hospital is the oldest and largest centre for ophthalmic treatment, teaching and research in Europe. Additional clinical centres across Europe enables broader patient outreach, increased opportunity to participate in the clinical trial, and paves the way for future commercialisation of the bionic vision system.

In parallel, Pixium Vision initiated last December CE mark approval process on the basis of IRIS clinical experience. Subject to CE mark approval timing, commercialisation is expected to start in H2 2016.

**Mahi Muqit, PhD FRCOphth, Consultant Ophthalmologist and Vitreoretinal Surgeon at Moorfields Eye Hospital, study Principal Investigator (UK)** said, *"We are excited to participate in the clinical trial of IRIS® II and be the first site in the UK. Patients with RP can now benefit from a new choice of retinal implant that may potentially further improve visual outcomes. This new clinical trial is key for ophthalmic reference centres like Moorfields to evaluate the latest technologies, and provide patients with a retinal implant that is differentiated and allows retinal implant exchanges in the future. We are delighted to work with Pixium Vision to develop solutions for retinal dystrophies like RP and age-related macular degeneration (AMD)."*

Commenting on the announcement, **Khalid Ishaque, CEO of Pixium Vision** said, *"The UK approval for the clinical study further reinforces our confidence in the IRIS® II platform, our first innovative bionic vision system."* **Khalid Ishaque** added: *"Currently as the only company developing an epi-retinal system for RP patients and a sub-retinal wireless photovoltaic implant for AMD patients, we are delighted to initiate this clinical partnership with the world renowned Moorfields Eye Hospital in the UK."*

IRIS® II epi-retinal system incorporates innovative features being evaluated, including:

- A **bio-inspired camera** that is intended to mimic the functioning of the human eye: the imaging sensor does not take sequence of video frames with 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 previously;
- An **explantable design**: the electrode array is secured on the retinal surface by a patented support system that allows to explant, minimising risk of retinal damage and permitting potential for upgrade to newer therapy options.

## About Moorfields Eye Hospital

Moorfields Eye Hospital NHS Foundation Trust is one of the world's leading eye hospitals, providing expertise in clinical care, research and education. We have provided excellence in eye care for more than 200 years and we continue to be at the forefront of new breakthroughs and developments. We are an integral part of one of the UK's first academic health science centres, UCL Partners, and now we are part of one of the first science health networks. We were 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 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://www.clinicaltrials.gov> Ref: NCT02670980*

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, 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.

Clinical trials are currently underway across multiple European centers:

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

**About Pixium Vision**  [www.pixium-vision.com](http://www.pixium-vision.com) ;  @PixiumVision;  [www.facebook.com/pixiumvision](http://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. They aim to enable patients who have lost their sight to lead more independent lives.

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

Pixium Vision, in parallel, is developing PRIMA also for Age-related Macular Degeneration (AMD) indication, a sub-retinal miniaturized wireless photovoltaic 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 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 (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 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)).*