



## **Pixium Vision receives approval from German Regulatory Authority to implant 150 electrode IRIS® II in clinical trial**

*IRIS® II, an innovative bionic vision system, equipped with a smart bio-inspired camera and a 150 electrode epi-retinal implant with an explantable design*

**Paris, France – February 16, 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 announces that it received approval from the German regulatory authority BfArM to initiate clinical trial for patients who have lost sight due to retinitis pigmentosa with the IRIS® II bionic vision system. This innovative system is composed of a bio-inspired camera and a 150 electrode epi-retinal implant with an explantable design.

The German approval follows the recent French and Austrian approvals. Consistent with its mission, Pixium Vision aims to offer patients best-in-class bionic vision system option.

For **Khalid Ishaque, CEO of Pixium Vision**, “The German approval for this clinical study reinforces our confidence in the IRIS® II platform, providing an innovative solution for patients suffering from retinitis pigmentosa.” **Khalid Ishaque**, added: “We are convinced the differentiated technical features of IRIS® II will provide meaningful benefits to these patients.”

Subject to CE mark approval timing, IRIS® II commercialization is expected to start in mid-2016.

IRIS® II incorporates innovative features, including:

- A **smart bio-inspired camera** that is intended to function like the human eye: the sensor does not take 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.

### **About Pixium Vision ([www.pixium-vision.com](http://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 (Compartment C) in Paris.  
ISIN: FR0011950641; Mnemo: PIX

IRIS® is a trademark of Pixium-Vision SA

### 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)"*

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.

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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](http://www.amf-france.org)) and of Pixium Vision ([www.pixium-vision.com](http://www.pixium-vision.com)).*