



## Pixium Vision receives approval from French Regulatory Authority to implant Iris® II in clinical study

*IRIS® II, a unique vision restoration system, equipped with a smart bio-inspired camera and a 150 electrode implant designed to be explantable and upgradeable*

**Paris, France – December 14, 2015 – 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 French regulatory authority ANSM to initiate clinical study for patients who have lost sight due to retinitis pigmentosa, with Iris® II Vision Restoration System (VRS), a unique epi-retinal implant with 150 electrodes, designed to be explantable and upgradeable.

This approval follows the clinical study with Iris® I, a VRS composed of an epi-retinal implant with 49 electrodes. Consistent with its strategy, Pixium Vision aims to offer patients best-in-class therapeutic option.

For **Khalid Ishaque, CEO of Pixium Vision**, “*This regulatory approval represents a major advance in the development of the IRIS® platform. Following epi-retinal clinical experience with IRIS® I, we now look to the future with an implant composed of almost 3 times more electrodes than the competing device.*” **Khalid Ishaque**, added: “*It is by pursuing parallel developments of hardware and software that we aim to continue to provide patients with best-in-class Vision Restoration Systems.*”

Subject to CE mark approval timing, IRIS® II commercialization is expected to start during the first half of 2016.

IRIS® II is incorporates differentiated and advanced technology, including:

- A **smart bioinspired camera** that functions like the human eye: the sensor does not take a sequence of pictures with redundancies but captures, in real time with its independent pixels, changes in visual events.
- An **epi-retinal implant with 150 electrodes**, almost three times more electrodes than the competing device. A higher number of electrodes allows more effective retinal stimulation.
- An **explantable design**: the electrode array is secured on the retinal surface by a patented support system that allows explantation, while minimizing risk of retinal damage and permitting potential for upgrade to newer therapy options.

In addition to the technology, the IRIS® platform has been conceived and designed to best respond to patient needs and facilitate adoption. The system was awarded with the Janus 2015 Prize for Health and the 2016 Observateur du Design label.

### About Pixium Vision ([www.pixium-vision.com](http://www.pixium-vision.com))

Pixium Vision is developing innovative Vision Restoration Systems (VRS) that aim to significantly improve the independence, mobility and quality of life of patients who have lost their sight. The Company harnesses the rapid advances in visual processing, microelectronics / nanoelectronics, optoelectronics, neurobiology and intelligent

software algorithms. Pixium Vision's VRS are associated with a surgical intervention as well as a rehabilitation period.

Clinical trials are currently underway with the VRS IRIS® in several centers in Europe. Patients have tolerated their implants well so far and improvements in visual perception have been observed. Pixium Vision plans to file IRIS's CE mark dossier before the end of 2015 and expects to launch IRIS® during the first half of 2016.

Pixium Vision is also developing PRIMA, a sub retinal implant currently in preclinical trial. The Company plans to begin clinical trials of PRIMA in Europe in 2016.

The company is ISO 13485 certified.



Pixium Vision is listed on Euronext (Compartiment C) in Paris.  
ISIN: FR0011950641; Mnemo: PIX

IRIS® is a trademark of Pixium-Vision SA

### About the IRIS® clinical study

The IRIS® II clinical trial is a multi-centric, open label, non-randomized prospective European study to assess safety and performance of the Vision Restoration 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)).*