



## Pixium Vision files for CE Mark for IRIS®II, its first Vision Restoration System

*A key step toward commercialization of IRIS® II, a unique system equipped with a smart bio-inspired camera and an implant with 150 electrodes, designed to be explantable and upgradeable*

**Paris, France – December 21, 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 had filed with its notified body an application for CE Mark for IRIS® II. The submission represents the last step towards obtaining authorization to commercialize the IRIS® II Vision Restoration System (VRS) in Europe.

Pixium Vision's application for CE Mark includes comprehensive information about the design (technical specifications), preclinical data, clinical evaluation and manufacturing for IRIS® II.

For **Khalid Ishaque, CEO of Pixium Vision**, "This regulatory filing for CE mark represents the culmination of years of research, development and testing efforts. It is a key milestone for Pixium Vision. We are now actively preparing for the commercial launch of the system across Europe." **Khalid Ishaque**, added: "We are convinced that the differentiated features of IRIS®II - a smart bioinspired camera that mimics functioning of the human eye and an implant with almost three times more electrodes than the competing device designed to be explantable and upgradeable- will bring enhanced independence and quality of life to patients with vision loss from retinitis pigmentosa."

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

Beyond the technological performance, IRIS® II was awarded with the Janus 2015 Prize for Health and the 2016 Observateur du Design label.

### About CE marking

CE Marking is a mandatory conformity marking for certain products sold within the European Economic Area, and is a declaration that the product meets the essential requirements of the applicable EC directives. For Active Implantable Medical Devices (AIMDs) like IRIS® II, CE Marking is granted by a Notified Body after review of the quality system and the design dossier for conformity to the AIMD 90/385/CEE Directive. Following CE Marking, a product can be sold in the EEA, and certain other countries.

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

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 EN 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

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## Disclaimer:

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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)).*