Pixium Vision announces CE market approval of IRIS®II, its first bionic vision system

CE mark certification enables market launch of Pixium Vision's innovative epi-retinal system equipped with a bio-inspired camera and a 150-electrode implant with a proprietary design intended to be explantable and upgradeable

Paris, France - July 25, 2016 – Pixium Vision (FR0011950641 - PIX), a company developing innovative bionic vision systems that aim to allow patients who have lost their sight to lead more independent lives, today announced that it has been awarded CE mark for its IRIS®II bionic vision system. This 150-electrode epi-retinal implant features a design intended to be explantable and upgradeable. The IRIS®II system is now CE mark approved for people with vision loss from outer retinal degeneration.

Christina Fasser, President of Retina International, an umbrella association of 33 national societies, said: "*The progress in research with vision restoration of some visual perception is a reality, particularly with retinal prostheses. This research is addressing the growing patients' expectations and their hope to regain some sight. On behalf of our member organisations, we are delighted to welcome the new bionic vision system IRIS®II that may offer people suffering from retinitis pigmentosa a new treatment option with a design that is intended to be explantable and upgradeable."*

IRIS®II incorporates innovative and distinctive features:

- A **bio-inspired camera** intended to mimic the functioning of the human eye by continuously capturing the changes in a visual scene with its time independent pixels, and unlike an imaging sensor that takes a sequence of video frames with largely redundant information;

- An **epi-retinal implant with 150 electrodes** – almost three times the number of electrodes than previous version;

- An **explantable** design: the electrode array is secured on the retinal surface by a patented support system that is intended to allow for explantation or future replacements or upgrades.

The IRIS®II system is only available by medical prescription. Several leading ophthalmology centers in Europe are continuing to evaluate the system's long-term performance based on a pre-defined protocol. The company is now able to file for national reimbursements.

Khalid Ishaque, CEO of Pixium Vision said: "*The CE mark certification is a major step forward for Pixium Vision and for retinal dystrophy patients who have lost their sight. This recognition, by an independent expert body, validates the long-term multidisciplinary work that has resulted in market approval of the IRIS®II system. We will continue to develop our bionic vision systems with the aim to deliver improved visual perception and help retinal dystrophy patients lead more independent lives."*

In parallel, Pixium Vision is developing a tiny, wireless, sub-retinal photovoltaic implant for patients with AMD (age-related macular degeneration).

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 CE mark

CE marking allows companies to legally market and distribute products within the European market and declares the product complies with all applicable European Directives and Regulations. For Active Implantable Medical Devices (AIMDs) like IRIS®II, CE Marking is granted by a Notified Body after review of design dossier and other information for conformity to the AIMD Directive. Following CE Marking, a product can be sold in the EEA, and certain other countries.

About Retinitis Pigmentosa (RP)

Retinitis Pigmentosa is the most common cause of inherited blindness with a prevalence of about 1.5 million people worldwide. In these patients, the degeneration of retinal cells often begins in their teen age years and the total loss of vision occurs in their 40s.
It is estimated that in Europe and the North America, approximately 350 000 to 400 000 people are affected by RP and that 15 000 to 20 000 new patients with RP lose their sight each year.

About PRIMA

PRIMA is the second system developed by the company. This tiny wireless photovoltaic sub-retinal implant has a modular structure and is currently in pre-clinical development. The company plans to launch clinical trials of PRIMA in Europe in 2016.

About Pixium Vision (www.pixium-vision.com ; @PixiumVision; 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.

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

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

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Pixium Vision is listed on Euronext (Compartiment C) in Paris.
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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) and of Pixium Vision (www.pixium-vision.com).