Pixium Vision receives clinical trial approval from Spanish Ministry of Health for 150 electrode IRIS®II bionic vision system

The prestigious Institute of Ocular Microsurgery (IMO) in Barcelona joins the clinical study 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 - 12 September 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, announced today that it has received approval from the Spanish Ministry of Health for clinical trial with the IRIS®II bionic vision system for patients who have lost sight due to Retinitis Pigmentosa (RP). The IRIS®II system features include a mini bio-inspired camera and a 150-electrode epi-retinal implant with an explantable design.

Barcelona's *Institute of Ocular Microsurgery* IMO (Spain) joins the expanding network of centres of excellence in Europe[1] involved in the clinical trial with IRIS®II. The Institute of Ocular Microsurgery is a world renowned ophthalmology center dedicated to the treatment of ocular diseases and the correction of vision. Patients in Spain will have the opportunity to participate in this European clinical trial.

Prof. Borja Corcostegui, Founder and Medical Director of the Institute of Ocular Microsurgery, IMO, a vitroretinal surgeon and the trial's principal investigator in Spain said: *"We are delighted to participate in the clinical trial with IRIS®II and become the first site in Spain. Patients blind from outer retinal degeneration in Spain can consider participation in assessing the innovative bionic vision system designed to regain a form of visual perception. Participation in clinical trials with innovative treatment options is essential for ophthalmology reference centres such as IMO. The partnership with Pixium Vision to develop solutions for retinal dystrophies, such as RP and, in the near future, Age-related Macular Degeneration (AMD), is consistent with our continuous commitment to offer cutting-edge treatment options to our patients."*

Khalid Ishaque, CEO of Pixium Vision said: *"The approval of the clinical trial now in Spain reinforces our confidence in the IRIS®II, our first bionic vision system. Today, Pixium Vision is the only company developing an epi-retinal implant system for retinitis pigmentosa, and a sub-retinal wireless photovoltaic implant for AMD patients. We are proud to initiate this clinical collaboration in Spain with the internationally renowned Institute of Ocular Microsurgery, IMO."*

In July 2016, Pixium Vision also received EU market approval for IRIS®II. Available under medical prescription, the bionic vision system offers a new treatment option to patients with retinitis pigmentosa. The Company can now also pursue reimbursement with the national healthcare systems. The ongoing prospective multi-centre clinical study protocol being conducted across several European ophthalmology reference centres, further enables building longer term evidence for the system performance.

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

[1] Clinical trial in European centres: http://www.pixium-vision.com/fr/essai_clinique/participating-centers

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.

About IMO Barcelona

IMO (Institute of Ocular Microsurgery) is a leading international ophthalmology centre, committed to medical excellence with the objective of providing the best service to the patient. For over 25 years, the Institute has sought to find solutions to all ocular disorders through the expert application of innovative technology and techniques.

On-going training and research, participating actively in clinical trials, enable IMO to discover new therapeutic opportunities and make advances in the diagnostic and treatment of eye problems in a pioneering and effective manner.

Its new premises, inaugurated in 2009 and boasting 70 consulting rooms and 8 operating theatres in an area of 22.000 square meters, have allowed IMO to become one of the biggest and most advanced centers in Europe. However, its hallmark is the medical team, led by 20 ophthalmologists sub-specialized in each part of the eye and the related pathologies. http://www.imo.es/en/

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 bionic system, in July 2016.

Pixium Vision is, in parallel, 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.

Pixium Vision is listed on Euronext (Compartiment C) in Paris.
ISIN: FR0011950641; Mnemo: PIX
IRIS® is a trademark of Pixium-Vision SA

Contacts

Pixium Vision
Pierre Kemula, CFO
investors@pixium-vision.com
+33 1 76 21 47 68
@PixiumVision

MediaRelations : Newcap Media
Annie-Florence Loyer - afloyer@newcap.fr
+33 1 44 71 00 12 / +33 6 88 20 35 59
Daphné Boccara - dboccara@newcap.fr
+33 1 44 71 94 93

Avertissement :

This press release may expressly or implicitly contain forward-looking statements relating to Pixium Vision and its activity. Such statements are related to known or unknown risks, uncertainties and other factors that could lead actual results, financial conditions, performance or achievements to differ materially from Vision Pixium results, financial conditions, performance or achievements expressed or implied by such forward looking statements.

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).

-