



## **Pixium Vision advances in review by the French health authority for eligibility of IRIS®II reimbursement under Forfait Innovation**

- **IRIS®II, recognized as an innovative device, qualifies for the first eligibility condition of “Forfait Innovation”**
- **Pixium Vision will complete its application for exceptional reimbursement with IRIS®II latest clinical data**

**Paris, May 24, 2017** – 7:30 CET - 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 the French Haute Autorité de Santé (HAS) has requested additional clinical data before completing the requirements for exceptional reimbursement (Forfait Innovation) for IRIS®II, its Bionic Vision System.

The HAS assessment committee recognized that IRIS®II system provides an innovative treatment and brings a new alternative for patients blinded by Retinitis Pigmentosa (RP) an insufficiently covered medical condition. IRIS®II thus successfully meets the first eligibility condition for the Forfait Innovation. The HAS requests that the dossier be completed with the latest clinical data. The HAS also recommends enhancing the post market clinical study protocol, proposed as part of the Forfait Innovation, to evaluate quality of daily living.

Pixium Vision will update the HAS with the latest available clinical follow-up data on IRIS® in RP. Initially, Pixium Vision will share the updated data which was presented during the recent French Ophthalmology Society (SFO) Congress, demonstrating the efficacy of IRIS® and its positive impact on patient's quality of life. The interim 6-month follow-up data from 10 patients who have been implanted with IRIS®II will also be provided when available. Finally, the additional recommendations of the HAS will be taken into considerations to enhance the post-market study protocol.

**Khalid Ishaque, CEO of Pixium Vision**, commented: *“We welcome the recognition of IRIS®II, our first CE marked bionic vision system, developed in France, as an innovative medical technology aiming to elicit bionic perception for patients having lost their vision to Retinitis Pigmentosa. The clinical studies follow-up with patient reeducation continues as planned and the initial safety and efficacy data among implanted patients are encouraging. We remain confident that provision of additional follow-up evidence to the HAS, together with constructive dialog on enhancing the post-market protocol, will meet the requirements for the IRIS®II system to be eligible for Forfait Innovation”.*

An innovative French company developing in parallel of two retinal bionic vision systems, Pixium Vision remains committed to advance, with continued constructive dialog with the regulatory and reimbursement authorities, to enable access, for patients having lost their sight to Retinitis Pigmentosa, to the IRIS®II bionic vision system and answer a medical need still insufficiently covered.

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## ABOUT PIXIUM VISION

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.

The company is developing two bionic retinal implant systems. IRIS®II, the company first bionic system, obtained CE mark in July 2016. In parallel, Pixium Vision has recently completed the pre-clinical study phases for PRIMA, a sub-retinal miniaturized wireless photovoltaic implant platform, and is planning to initiate first-in-human trials.

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. The company is EN ISO 13485 certified.

For more information, please visit:  [www.pixium-vision.com](http://www.pixium-vision.com);

And follow us on:  @PixiumVision;  [www.facebook.com/pixiumvision](http://www.facebook.com/pixiumvision)

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Pixium Vision is listed on Euronext Paris (Compartment C). Pixium Vision shares are eligible for the French tax incentivized PEA-PME and FCPI investment vehicles.

Pixium Vision is included in the Euronext CAC All Shares index

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

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