Pixium Vision receives FDA approval to begin human clinical study of its PRIMA sub-retinal implant in the US

The feasibility clinical study is designed to evaluate PRIMA in patients with Atrophic Dry Age-related Macular Degeneration

Paris, France. January 4, 2018 – 7.00 AM CET - Pixium Vision (FR0011950641 - PIX), a company developing innovative bionic vision systems to enable patients who have lost their sight to lead more independent lives, announced today that it has received the approval from the US Food and Drug Administration (FDA) to begin the clinical feasibility study for PRIMA, Pixium Vision's new-generation miniaturized wireless photovoltaic sub-retinal implant, in patients with Atrophic Dry Age-related Macular Degeneration (AMD).

"*This first approval in the US will allow Pixium Vision to commence a feasibility study of the PRIMA device and follows a thorough review by the FDA. It also highlights the FDA's recognition of PRIMA's innovative potential to address the significant unmet need to treat Atrophic Dry-AMD," said* **Khalid Ishaque**, **Chief Executive Officer of Pixium Vision.** *"Atrophic Dry-AMD is a major cause of irreversible loss*[1] *of the vision which affects approximately 4 million people and for whom there is currently no proven therapeutic solution. Alongside the ongoing clinical trial in France, the feasibility study in the United States marks a significant milestone for Pixium Vision with the mission to create a world of bionic vision for those who have lost their sight."*

The clinical feasibility study of PRIMA implant, to be conducted at the University of Pittsburgh Medical Center, will recruit up to five patients with vision loss that results from Atrophic Dry Age-related Macular Degeneration. The primary endpoint is restoration of visual perception as well as safety at a 12-month follow-up with a longer-term follow-up duration of 36 months. Pixium Vision expects to start the US study in the first half of 2018.

[1] http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(17)30393-5/fulltext

Contacts

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

Media Relations
France: Newcap Media
Annie-Florence Loyer - afloyer@newcap.fr
+33 1 44 71 00 12 / +33 6 88 20 35 59
Léa Jacquin - ljacquin@newcap.fr
+33 1 44 71 94 94

Media Relations
International: Image Box PR
Neil Hunter
neil@imageboxpr.co.uk
Tel +44 (0)20 8943 4685

ABOUT PRIMA

PRIMA is a miniaturized new generation implant totally wireless. The PRIMA implant is a micro photovoltaic chip of 2x2 millimeters and 30 microns thick, and is equipped with 378 electrodes. Implanted under the retina via a less invasive surgical procedure, the implant converts pulsed near infra-red light signal received from the external glasses with an integrated mini-camera into electrical signals transmitted to the brain via the optic nerve. PRIMA is designed to treat retinal dystrophies, particularly aiming to treat initially advanced atrophic dry-AMD, the most prevalent form of Age-related Macular Degeneration, thanks to miniaturization and aimed to preserve patient's residual peripheral vision. Prima is also intended to be evaluated at a later stage for treatment of vision loss from Retinitis Pigmentosa.

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. Following the CE mark for its first bionic retinal implant systems, IRIS®II, Pixium Vision is now conducting a clinical study in Human with PRIMA, its next generation sub-retinal miniaturized photovoltaic wireless implant system, for patients who have lost their sight due to outer retinal degeneration, initially for atrophic dry age-related macular degeneration (dry AMD). 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, Moorfields Eye Hospital in London, and Institute of Ocular Microsurgery (IMO) in Barcelona. Pixium Vision is EN ISO 13485 certified and labeled "Entreprise Innovante" by Bpifrance

For more information, please visit: www.pixium-vision.com;
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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) and of Pixium Vision (www.pixium-vision.com).

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