



Pixium Vision receives approval for First-in-Human Clinical Trial of PRIMA, its miniaturized sub-retinal implant

French regulatory Authority, ANSM, approves PRIMA's feasibility study for advanced dry-AMD

Paris, France. October 19, 2017 – 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, today announces that its next-generation miniaturized wireless sub-retinal implant, PRIMA, to restore vision in patients affected by retinal dystrophies, received authorization from the French regulatory agency, *Agence Nationale de Sécurité du Médicament et des Produits de santé* (ANSM), to start a feasibility clinical study in patients with advanced dry age-related macular degeneration (dry-AMD).

Khalid Ishaque, Chief Executive Officer of Pixium Vision, commented: "*The approval of the clinical study is a significant advance for the PRIMA system, our next generation wireless sub-retinal implant system, as well as for Pixium Vision. Conceived initially by the researchers at Stanford University, and successfully developed through to clinical stage by our team at Pixium Vision in close collaboration with numerous physicians and scientists, PRIMA enters an exciting phase of its development, with a first patient expected to be implanted before year end. With ageing population dynamics, advanced dry-AMD is a leading cause of irreversible vision loss¹ with currently estimated over 4 million people without approved treatment option making it a significant unmet medical need.*"

The clinical study entitled "*Feasibility Study of Compensation for blindness with the PRIMA system in patients with dry age related macular degeneration*", is designed to evaluate the tolerance of PRIMA and to demonstrate the evoked central visual perception among patients who have lost their sight due to atrophic advanced dry-AMD. The study is planned to recruit 5 patients with interim evaluation at 6-month follow-up and longer term follow-up to 36 months. The study will be conducted at *Fondation Ophtalmologique Rothschild* and *Hôpital des Quinze-Vingt* in Paris with Dr. Yannick Le Mer, vitreoretinal surgeon and ophthalmologist, as principal investigator.

In parallel, Pixium Vision actively pursues its constructive discussions with the US Food and Drug Administration (FDA), in order to also prepare the feasibility study with PRIMA in the US.

¹ [http://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(17\)30393-5/fulltext](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 2 millimeters and 30 microns thick, PRIMA is equipped with 378 electrodes. Implanted under the retina via a less invasive surgical procedure, implant converts pulsed near infra-red invisible 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 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 has been authorized to start clinical study in Human for PRIMA, a sub-retinal miniaturized wireless implant system. 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. Pixium Vision is qualified "Entreprise Innovante" par Bpifrance

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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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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).

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