Pixium Vision advances in discussions with FDA for a feasibility study with its PRIMA system for Dry-AMD

- **Clinical evaluation of PRIMA being assessed for early feasibility study program in the US**
- **The early feasibility study may be pursued for patients suffering from advanced dry age-related macular degeneration (Dry-AMD), a significant unmet need**

Paris, 13 June 2017 – 7:00 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, continues its constructive dialogue with the US Food and Drug Administration (FDA), in order to prepare the first-in-human study with PRIMA, its miniaturized wireless sub-retinal photovoltaic implant system.

The pre-clinical dossier for PRIMA was strengthened with additional in-vivo animal data presented during the latest world congress of the Association for Research in Vision and in Ophthalmology (ARVO) in May, including non-human primate behavioral results. The latest data was also discussed with the FDA within the framework of U.S. regulatory process. Pixium Vision is currently preparing submissions for an Early Feasibility Study program for treating dry-AMD. Early feasibility studies allow for early clinical evaluation of devices, in a limited number of patients, to provide proof of principle and initial clinical safety data.

Khalid Ishaque, CEO of Pixium Vision, commented: *« We remain in constructive dialogue with the FDA to prepare for the authorization for a first-in-human clinical study for PRIMA. The nature of the strict regulatory processes often requires additional data from the regulatory authorities, particularly for first-in-human studies. Given the important technological innovation and advances expected from the PRIMA system, Early Feasibility Study path has been considered more appropriate than the Expedited Access Pathway (EAP) for first in human in the US. Our latest pre-clinical data, including the results presented during ARVO 2017, provided additional confidence and enabled FDA to continue to assess both safety and therapeutic potential of PRIMA for dry-AMD indication.».*

Pixium Vision actively pursues the development of its PRIMA system and continues to enrich the discussions with European and U.S. regulatory authorities aiming for clinical feasibility study in Human within 2017.

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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;
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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).