PRESS RELEASE

Pixium Vision receives French regulatory authority (ANSM) approval to initiate European PRIMAvera pivotal study of Prima System

Paris, November 20, 2020 – 07.00 CET– Pixium Vision (**Euronext Growth Paris - FR0011950641**), a bioelectronics company that develops innovative bionic vision systems to enable patients who have lost their sight to live more independently, today announces it has received approval from the French regulatory health authority, ANSM, to initiate its PRIMAvera European pivotal study of its bionic vision Prima System for atrophic dry age-related macular degeneration (AMD).

The PRIMAvera study, which Pixium Vision expects to start by the end of 2020, will aim to confirm the safety and the benefits provided by the Prima System and is the last clinical step before seeking market approval in Europe. The Prima System will be studied in 38 patients in this open label, baseline-controlled, non-randomized, multi-center, prospective, single-arm confirmatory trial.

The primary efficacy endpoint is the proportion of subjects with an improvement of visual acuity of logMAR 0.2 or more from baseline to 12 months, and the primary safety endpoint is the number and severity of device and procedure related serious adverse events at 12 months follow-up. The study will include three years of follow-up, with assessment of the primary endpoints at 12 months after implantation.

The PRIMAvera pivotal study design is based on the data generated in the French feasibility study, showing the ability of patients with dry AMD to improve in visual acuity with the Prima system compared to without the system. Patients had a significant improvement in vision, gaining on average a logMAR of 0.5 (corresponding to 5 lines improvement) which may make the difference between recognizing letters on a street sign or not. Pixium Vision also expects to report 36-month data of this feasibility study by mid-2021.

"We are absolutely delighted to receive this approval in France to initiate our European PRIMAvera pivotal trial, which the Pixium Vision team has worked diligently to prepare. This is an important step toward CE mark of the Prima System, which has shown excellent results in improving patients' vision and demonstrated the potential to significantly enhance the independence and quality of life of people suffering from dry AMD, who currently have no treatment options," said **Lloyd Diamond, Chief Executive Officer of Pixium Vision**. Mr. Diamond further commented that "*this is the first competent authority approval in Europe which will likely help ensure approvals by other European countries to participate in the study, the filing process of which is already underway*."

"*It is tremendously exciting to have a green light to initiate this important study. The results to date are extremely encouraging and the PRIMAvera study will provide further insight into the impact of the Prima System on how these patients go about their daily lives,"* said **Dr Yannick Le Mer, Head of Vitreo-retinal Unit at Fondation Adolphe de Rothschild Hospital in Paris and principal investigator of the trial**.

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Pixium Vision is creating a world of bionic vision for those who have lost their sight, enabling them to regain visual perception and greater autonomy. Pixium Vision's bionic vision systems are associated with a surgical intervention and a rehabilitation period. Prima System sub-retinal miniature photovoltaic wireless implant is in clinical testing 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, including some of the most prestigious vision research institutions in the world, such as: Stanford University in California, Institut de la Vision in Paris, Moorfields Eye Hospital in London, Institute of Ocular Microsurgery (IMO) in Barcelona, University hospital in Bonn, and UPMC in Pittsburgh, PA. The company is EN ISO 13485 certified and qualifies as "Entreprise Innovante" by Bpifrance.

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Pixium Vision shares are eligible for the French tax incentivized PEA-PME and FCPI investment vehicles.

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