

Pixium Vision announces regulatory approval of remote rehabilitation system for patients in clinical trials

- Remote rehabilitation approved in France, Germany, Italy, Spain and the Netherlands
- First feature of new remote patient engagement platform allows completion of most of the post-implantation training at home
- PRIMAvera pivotal trial of Prima System on track to read-out around end-2023

Paris, France, August 3, 2022 – 07:00 CET – Pixium Vision SA (Euronext Growth Paris - FR0011950641; Mnemo: ALPIX), a bioelectronics company that develops innovative bionic vision systems to enable patients who have lost their sight to live more independent lives, announces today the approval of the remote rehabilitation system for patients enrolled in the PRIMAvera pivotal trial and the French Feasibility Study in atrophic dry age-related macular degeneration (AMD). The approval was granted by the Ethics Committee and the Regulatory Authorities.

This first feature of Pixium Vision's new remote patient engagement platform will allow patients to conduct rehabilitation sessions from home, with or without the help of a family member or a caregiver. The platform requires only a tablet, provided by Pixium, and an internet connection to be fully functional. Over the coming months, more innovative features are expected to be added to the platform to help dry AMD patients live a more independent life.

The PRIMAvera study aims to confirm the safety as well as the benefits provided by the Prima System and is the last clinical step before seeking market approval in Europe. The study was initiated in Q4 2020 in France, and the first patient was implanted in March 2021. Pixium Vision has since established clinical sites and implanted its first patients in Germany, the UK and the Netherlands. The opening of additional clinical sites is planned in Spain, and Italy during 2022. Pixium Vision expects to complete recruitment by the end of 2022, leading to a read-out of the PRIMAvera study around the end of 2023 and a regulatory submission in Europe in H1 2024.

"The approval of the remote rehabilitation allows patients enrolled in our PRIMAvera pivotal study and French Feasibility Study to complete the majority of their training in the comfort of their own homes with a simple technical set up and without the need for repeated trips to hospital," said **Lloyd Diamond, Chief Executive Officer of Pixium Vision.** "We are using apps specifically designed for our patients as well as employing gamification principles to make the rehabilitation process as engaging and effective as possible. We also expect the remote patient engagement platform, thanks to upcoming additional functionality, to encourage better communication between patients and their physicians and among patients themselves. Over the last few months, we have successfully continued to move the Prima System closer to the market and this remote rehabilitation process will be a critical element of the real-life process once this revolutionary system is commercialized in a couple of years."

Remote rehabilitation has been approved in France, Germany, Italy, Spain and the Netherlands for patients who have succesfuly completed their initial in-clinic rehabilitation sessions. The remote rehabilitation sessions will take place between the patient and the rehabilitation specialists and will be of the same nature as the inclinic rehabilitation sessions. The platform will also allow clinicians to track the progress of patients at any time and to adjust the frequency of the remote rehabilitation sessions based on the progress of each patient. Given the age and lack of vision of the patients enrolled in the clinical studies, remote rehabilitation will make it simpler for patients to comply. Pixium Vision's unique remote patient engagement platform is a tailor-made solution to ensure appropriate rehabilitation.

"In order to achieve the best visual function following implantation, it is paramount for patients to adhere to a comprehensive rehabilitation process. Getting patients fully engaged in this rehabilitation process will secure the best results. The new remote rehabilitation module of the PRIMAvera trial allows patients to train daily at

home, thus decreasing the burden of frequent in-office sessions. This would be a hybrid rehabilitation scheme mixing in-person rehabilitation sessions with supervised remote home training. Recent developments are making the remote training system increasingly easier to use and patient-friendlier," said **Dr. Villani, Director of the Low Vision and Microperimetry Center of Verona "C.R.I.M." (Centro Riabilitazione Ipovedenti e Microperimetria – Verona, Italy)**. "Also, the gaming nature of some training exercises – as well as the ability to communicate easily with physicians, nurses, family members and other patients – will further motivate patients to engage in the training and allow physicians to better track progress and adapt the rehabilitation as needed. The platform will also help us researchers gather precious information to further improve the training over time."

A total of 38 patients will be enrolled in the PRIMAvera study, an open-label, baseline-controlled, nonrandomized, multi-center, prospective, single-arm pivotal 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 an assessment of the primary endpoints at 12 months after implantation.

About Pixium Vision

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.

Forward-Looking Statements. This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward looking statements, please refer to the Risk Factors ("Facteurs de Risques") section of the Company's 2021 Half-Year Financial Report and other documents the Company files with the AMF, which is available on the AMF website (www.amf- france.org) or on the Company's website.

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Pixium Vision is listed on Euronext Growth Paris. Euronext ticker: ALPIX - ISIN: FR0011950641

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

Pixium Vision is included in the Euronext GROWTH ALLSHARE index

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