



Kubota Vision Announces CRB Approval for a Specific Clinical Trial Using eyeMO at Shinshu University Hospital

Seattle (May 6, 2024) — Kubota Vision Inc. (“Kubota Vision” or the “Company”), a clinical-stage specialty ophthalmology company and a wholly-owned subsidiary of Kubota Pharmaceutical Holdings Co., Ltd. (Tokyo 4596), today announced the CRB approval by the Accredited Clinical Research Review Committee for a specific clinical study using eyeMO^{*1}, a portable, low-cost, home-based, remote and in-office ophthalmic OCT^{*2} device for monitoring of retinal diseases.

After a feasibility study, this study, sponsored by Chugai Pharmaceutical Co. Ltd., will be conducted at Shinshu University Hospital. It will evaluate whether the device can be used at home in patients with diabetic macular edema. In addition, the validity of retinal thickness measurements and measurements of retinal status will be used to determine the presence of intra- and subretinal edema.

Ryo Kubota, MD, PhD, Chairman, President, and CEO of Kubota Vision Inc., stated, “Aiming to promote world-leading home care in the field of ophthalmology, we have developed eyeMO, a state-of-the-art retinal monitoring device that contributes to improving patient prognosis. We are very pleased that Shinshu University Hospital has decided to validate this device, giving us the opportunity to use our technology in an even wider range of applications.”

This transaction will have no impact on the Company's consolidated financial results for the fiscal year ending December 31, 2023.

^{*1} eyeMO is a product name for the Patient Based Ophthalmology Suite (PBOS).

^{*2} Optical Coherence Tomography (OCT) is a non-invasive tool that uses light waves to take cross-section pictures of the retina.

About eyeMO

eyeMO is a low-cost, home-based, ophthalmic self-monitoring OCT device. This small handheld device addresses needs in mobile Health (mHealth^{*3}) applications for self-monitoring of retina health by patients in the home and in remote field locations. eyeMO aims to improve ophthalmic treatment outcomes in patients diagnosed with and treated for wet age-related macular degeneration (AMD), diabetic macular edema (DME), and other neovascular retinal diseases. eyeMO is being designed to detect nascent disease progression and support patient re-treatment prior to irreversible vision loss due to disease progression. Key features are low cost and a patient-friendly design to be used directly by patients at home. eyeMO is being designed to capture changes in retinal anatomy. Network connectivity and cloud-based technologies are used to alert the patients and their physicians of disease progression and re-treatment needs.

^{*3} mHealth refers to the usage of mobile communications technology and devices to enhance access to healthcare information, improve distribution of routine and emergency health services, and provide diagnostic services.

About Kubota Vision Inc.

Kubota Vision Inc. is a wholly owned subsidiary of Kubota Pharmaceutical Holdings Co., Ltd. (Tokyo 4596), committed to translating innovation into a diverse portfolio of drugs and devices to preserve and restore vision for millions of people worldwide. Kubota Pharmaceutical group's pipeline includes a wearable device for myopia control using Kubota Glass technology and a handheld OCT device for the monitoring of neovascular retinal diseases, to be used directly by patients. <https://www.kubotavision.com/>; <https://www.kubotaholdings.co.jp/en/>

Cautionary Statements

Certain statements contained in this press release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include statements regarding our expectations related to our development plans and ability to successfully develop and commercialize our product candidates and the potential efficacy, future development plans and commercial potential of our product candidates. These statements are based on current assumptions that involve risks, uncertainties and other factors that could cause the actual results, events or developments to differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: our investigational product candidates may not demonstrate the expected safety and efficacy; our pre-clinical development efforts may not yield additional product candidates; any of our or our collaborators' product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; our clinical trials could be delayed; new developments in the intensely competitive ophthalmic pharmaceutical market may require changes in our clinical trial plans or limit the potential benefits of our investigational product candidates; the impact of expanded product development and clinical activities on operating expenses; adverse conditions in the general domestic and global economic markets; as well as the other risks identified in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements. For a detailed discussion of the foregoing risks and other risk factors, please refer to our filings with the Securities and Exchange Commission, which are available on Kubota Pharmaceutical Holdings (Kubota Vision's parent company) investor relations website (<https://www.kubotaholdings.co.jp/en/ir/>) and on the SEC's website (<http://www.sec.gov>).

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