Press Release

Kubota Vision Announces Clinical Study Agreement with Insel Gruppe AG for PBOS

Seattle (August 19, 2020) — Kubota Vision Inc. (Kubota Vision), a clinical-stage ophthalmology company and wholly-owned subsidiary of Kubota Pharmaceutical Holdings Co., Ltd. (Tokyo 4596), today announced that the company and Insel Gruppe AG have entered into a clinical study agreement for our Patient Based Ophthalmology Suite (PBOS), in-home optical coherence tomography (OCT) device, with 3D imaging capabilities using artificial intelligence (AI).

Insel Gruppe AG will conduct a clinical study to evaluate in subjects with normal macular thickness and subjects with center-involving macular edema the PBOS with 3D imaging capabilities using AI. The 3D imaging assists in the detection of fluid buildup within and under the retina of the eye.

Insel Gruppe AG is one of the leading companies located in Bern, Switzerland that innovates with the latest technologies and provides full-service medical care system with over 10,000 employees from around 80 different countries. The clinical study will be supervised by Dr. Marion Munk, MD, PhD., as the Principal Investigator. Dr. Munk is a retina specialist at the University of Bern in Switzerland and has over 10 years of clinical expertise in retina, uveitis and clinical imaging and as consultant for many key players in the ophthalmology drug and device development space.

Ryo Kubota, MD, PhD, Chairman, President and CEO of Kubota Vision Inc., stated, “3D imaging on PBOS is one of the key features needed to discuss partnership opportunities. Together with Insel Gruppe AG, we will validate the 3D imaging capabilities and continue working on it to improve the software. Our PBOS is a small, light-weighted, low-cost device that provides 3D images of the location and structure of retinal edema. We believe that our technology will enhance the quality of patient care in the teleophthalmology field.”

A commercial OCT device is large and expensive, and mainly used at large eye clinics/centers and laboratories; however, our PBOS is a home-based, patient-friendly, ophthalmic self-monitoring miniature OCT device designed to detect disease progression. It uses network connectivity and cloud-based technologies to share images and alert patients and their physicians of disease progression and re-treatment needs, without requiring physician office visits.

Kubota Vision completed a successful clinical study in October 2018 that demonstrated the PBOS could detect thinning and thickening of the human retina over time, when compared to results from an established commercial OCT device. The first fully-functional, working PBOS prototypes have been completed, and the company is currently in the process of further improving the software including 3D imaging capabilities while exploring partnership opportunities for commercialization.

About PBOS

PBOS (Patient Based Ophthalmology Suite) is a low cost, home-based, ophthalmic self-monitoring OCT device. This small handheld device addresses needs in mobile Health (mHealth[*2]) applications for self monitoring of retina health by patients, in the home and in remote field locations.

The PBOS 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. PBOS 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. PBOS 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.

[*1] OCT (Optical Coherence Tomography) is a non-invasive tool that uses light waves to take cross-section pictures of the retina.

[*2] 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 development pipeline include drug candidates for the treatment of diabetic retinopathy, Stargardt disease, and optogenetics-based gene therapy for the treatment of retinitis pigmentosa. The company is also developing a handheld OCT device for the monitoring of neovascular retinal diseases, to be used directly by patients, and wearable device for myopia control.
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).

Media and Investor Relations Contact:

Hiroki Maekawa
Chief Financial Officer
Phone: +81-3-6550-8928
Email: pr@kubotaholdings.co.jp

# # #