Press Release

Kubota Vision Announces Top-Line Results from Phase 3 Clinical Trial of Emixustat in Patients with Stargardt Disease

SEATTLE (August 11, 2022) — Kubota Vision Inc. ("Kubota Vision"), a clinical-stage ophthalmology company and wholly-owned subsidiary of Kubota Pharmaceutical Holdings Co., Ltd. (Tokyo 4596), announced today top-line results from the Phase 3 clinical trial of the investigational visual cycle modulator emixustat hydrochloride (emixustat) in patients with Stargardt Disease.

The primary objective of this study was to determine if emixustat reduces the rate of macular atrophy progression, in comparison to placebo, in subjects with Stargardt disease. The top-line results showed that the study did not achieve its primary or secondary endpoints and did not demonstrate meaningful differences between treatment groups. For the primary endpoint, the macular atrophy progression rate was 1.280 mm^2/year with emixustat compared to 1.309 mm^2/year with placebo (p=0.8091). Emixustat was well-tolerated and demonstrated a safety profile consistent with prior studies.

The study was a multi-center, randomized, double-masked, and placebo-controlled phase 3 clinical study in which subjects were randomly assigned to emixustat 10 mg or placebo (2:1 ratio) once daily for 24 months. The total target number of subjects was 162; however, due to high interest in the study, a total of 194 subjects were enrolled in this study across 29 sites in 11 countries worldwide.

Ryo Kubota, MD, PhD, Chairman, President, and CEO of Kubota Vision Inc., stated, "While we sincerely regret that we were unable to achieve the results we had initially hoped for, we will further closely examine the data obtained from this clinical trial and determine the next steps including partnership opportunities. We continue focusing on medical device development and commercialization with our leading device of Kubota Glass. In order to meet the expectations of our shareholders and stakeholders as quickly as possible, we will create a business environment that allows us to concentrate on medical device development and commercialization."

The Company is carefully examining the impact on the consolidated earnings forecast for the fiscal year ending December 31, 2022 (January 1, 2022 to December 31, 2022) and will be promptly disclosed if a revision to the financial forecast becomes necessary.

About Funding for this Clinical Trial

As previously announced in August 2020, the FDA Office of Orphan Products Development (OOPD) awarded Kubota Vision an orphan products clinical trial grant to support this clinical trial. Specifically, this clinical trial was supported by the FDA of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award (FAIN: R01FD006849) totaling $1,633,917 with 6.7% funded by FDA/HHS and $22,858,571 (93.3%) funded by Kubota Vision. The contents of this press release are those of Kubota Vision and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

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 includes drug candidates for the treatment of diabetic retinopathy and Stargardt disease. The Company is also developing a handheld OCT device for the monitoring of neovascular retinal diseases, to be used directly by patients, and a 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:

Press and Media Inquiries
Phone: +81-3-6550-8928
Email: pr@kubotaholdings.co.jp

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