ACUCELA

News Release

Acucela Completes PBOS Clinical Study and Validates Concept

SEATTLE (October 28, 2018) — Acucela Inc. ("Acucela"), a clinical-stage ophthalmology company and wholly-owned subsidiary of Kubota Pharmaceutical Holdings Co., Ltd. (Tokyo 4596), announced today the successful completion of a clinical study which aimed to measure retinal thickness in patients with macular edema using PBOS (low cost, home-based, ophthalmic self-monitoring OCT[*1] device) engineering prototype.

The study was a single-center clinical study which aimed to measure retinal thickness using PBOS, evaluating 12 subjects with normal macular thickness and 20 subjects with center-involving macular edema. The study evaluated the repeatability of retinal thickness measurements, the ability to detect changes in retinal thickness over time, and, correlation of retinal thickness measurements by PBOS and a hospital-grade OCT unit.

Acucela has completed a successful clinical study that demonstrated PBOS could detect thinning and thickening of the human retina over time, when compared to results from an established commercial OCT.

Dr. Ryo Kubota, MD, PhD, and Chairman, President and CEO of Acucela stated that, "To receive proper treatment for retinal diseases, it is important to understand changes in retinal condition over time. With the PBOS, I believe that patients and their family may be able to actively be involved in the treatment process of retinal diseases that may lead to blindness."

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.

In its first iteration, the PBOS aims to improve ophthalmic treatment outcome 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 patient-friendly design, to be used directly by patients at home. PBOS will be used to capture changes in retinal anatomy and can also provide visual function monitoring to assess changes in visual acuity. 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 Acucela Inc.

Acucela 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. Acucela's development pipeline include drug candidates for the treatment of diabetic retinopathy, diabetic macular edema, Stargardt disease, age-related macular degeneration, cataracts and presbyopia, 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. http://www.acucela.com; http://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 (Acucela's parent company) investor relations website (http://www.kubotaholdings.co.jp/en/ir/) and on the SEC's website (http://www.sec.gov).

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