

FINAL RELEASE

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Acucela and Otsuka Pharmaceutical Receive FDA Fast Track Designation for ACU-4429 in Patients with Dry AMD

Novel, Oral Therapy in Phase 2 Clinical Trial for Dry AMD, A Leading Cause of Blindness in People Over Age 50

Bothell, Wash. and Tokyo, Japan (March 17, 2010) – Acucela Inc., a clinical-stage biotechnology company focused on developing new treatments for blinding eye diseases, and Otsuka Pharmaceutical Co., Ltd., today announced that they have received Fast Track designation from the U.S. Food and Drug Administration (FDA) for ACU-4429, an investigational oral treatment for dry age-related macular degeneration (dry AMD). The FDA's Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track designated programs may be eligible for priority regulatory review by the FDA.

After presenting successful Phase 1 data at several medical conferences in 2009, Acucela and Otsuka Pharmaceutical launched the ENVISION Clarity Trial, a Phase 2 clinical trial of ACU-4429 in patients with dry AMD in January 2010. ACU-4429 is one of the only treatments in development that works to slow the eye's visual cycle for processing light. By slowing this cycle, ACU-4429, in the preclinical studies, has demonstrated the ability to decrease the levels of toxic by-products in the eye and thereby potentially stop the advance of dry AMD. Dry AMD is a leading cause of vision loss in people over the age of 50, yet there are no therapies currently approved to treat this condition.

“We are very pleased to receive this Fast Track designation from the FDA for ACU-4429 for the treatment of dry AMD,” stated Ryo Kubota, M.D., Ph.D., chairman, president and chief executive officer of Acucela. “We believe that ACU-4429 may represent a new approach to treating dry AMD and other degenerative eye diseases and, for those patients losing their vision, this designation is critical as it can accelerate our clinical programs. We look forward to advancing the ACU-4429 program, along with our strategic partner Otsuka Pharmaceutical, and providing ongoing updates to the researchers, physicians and patients who are so eagerly searching for a safe and effective treatment for dry AMD.”

AMD occurs in “dry” and “wet” forms, which together are estimated to affect more than 29 million people worldwide, according to the 2007 Visiongain report, “The AMD Report (2007-2012).” This number is expected to double in the next 20 years due to the aging population. About 90 percent of AMD patients – or 26 million people – suffer from dry AMD, a degenerative disease that affects the part of the retina responsible for fine visual acuity and color vision.

About the ENVISION Clarity Trial

The ENVISION (Evaluating a Novel VISION treatment for AMD) Clarity Trial is part of the clinical program evaluating the investigational oral treatment ACU-4429 in patients with dry age-related macular degeneration (dry AMD). The Clarity Trial, a Phase 2 clinical trial of ACU-4429 in patients with dry AMD, was launched in January 2010 and builds upon the promising preclinical findings and initial data from Acucela’s Phase 1 clinical studies. These initial Phase 1 data have been presented at the Association for Research in Vision and Ophthalmology (ARVO) 2009 Annual Meeting, the Aegean Retina XI Meeting and the 8th International Symposium on Ocular Pharmacology and Therapeutics (ISOPT) and demonstrate the safety and tolerability of ACU-4429 in healthy volunteers aged 55-80. In addition, these data mark the first time that a non-retinoid therapeutic in a convenient pill form has effectively targeted the visual cycle in a dose-dependent manner.

About ACU-4429

ACU-4429 utilizes Acucela’s proprietary visual cycle modulation (VCM) technology, and is designed to prevent or inhibit the generation of toxic by-products of the visual cycle that can lead to degenerative eye conditions like dry AMD. Preclinical data indicate that ACU-4429 slows the rod visual cycle, resulting in decreased accumulation of a toxic by-product that is the precursor of lipofuscin, which are deposits of toxic substances. The chronic accumulation of lipofuscin has been implicated in degenerative retinal diseases. ACU-4429 is administered to patients as an oral, daily pill rather than by injection into the eye, which is typical of many current eye therapeutics. Otsuka Pharmaceutical and Acucela have forged a strategic partnership to co-develop ACU-4429 in dry AMD as well as other potential indications in North America.

About Acucela Inc.

Acucela Inc. is a clinical-stage biotechnology company focused on leveraging promising science in visual cycle modulation (VCM) to develop new methods for treating blinding eye diseases that affect tens of millions of people worldwide. The company’s orally-delivered VCM therapies, which selectively target cells within the retina to protect visual acuity, have the potential to be used to treat several devastating eye diseases, including dry age-related macular degeneration (AMD), retinopathy of prematurity, Stargardt disease and diabetic retinopathy. Acucela is also developing, with Otsuka Pharmaceutical, Rebamipide ophthalmic suspension, a product candidate for dry eye. For more information, please visit www.Acucela.com.

About Otsuka Pharmaceutical

Founded in 1964, Otsuka Pharmaceutical Co., Ltd. is a global healthcare company with the corporate philosophy: 'Otsuka-people creating new products for better health worldwide.' Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products for the treatment of diseases and consumer products for the maintenance of everyday health. Otsuka is committed to being a corporation that creates global value, adhering to the high ethical standards required of a company involved in human health and life, maintaining a dynamic corporate culture, and working in harmony with local

communities and the natural environment. Otsuka Pharmaceutical Co., Ltd. is a wholly owned subsidiary of Otsuka Holdings Co., Ltd., the holding company for the Otsuka Group. The Otsuka Group comprises 153 companies and employs approximately 36,000 people in 23 countries and regions worldwide. Otsuka and its consolidated subsidiaries earned ¥955.9 billion (approx. US \$9.7 billion^{*}) in annual revenues in fiscal 2008.

* Exchange rate as of March 31, 2009.

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