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Acucela Launches ENVISION Clarity Trial; Initiates Phase 2 Clinical Trial of Oral Visual Cycle Modulator in Patients with Dry Age-Related Macular Degeneration

ACU-4429 Slows the Visual Cycle and Represents New Approach to Treating Leading Cause of Blindness in People Over 50; No Therapy Currently Approved

BOTHELL, Wash. (January 13, 2010) – Acucela, a clinical-stage biotechnology company focused on developing new treatments for blinding eye diseases, today announced the launch of its ENVISION Clarity Trial, a Phase 2 clinical trial of ACU-4429, an investigational oral treatment for dry age-related macular degeneration (dry AMD). 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 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 be initiating our first Phase 2 clinical trial of ACU-4429 for the treatment of dry AMD,” stated Ryo Kubota, M.D., Ph.D., chairman, president and chief executive officer of Acucela and discoverer of the gene that causes glaucoma. “Our preliminary Phase 1 data - presented at ARVO 2009 and the Aegean Retina XI conference last year - are extremely promising and demonstrate the safety and tolerability of ACU-4429, as well as its ability to effectively slow the eye's visual cycle in a dose dependent manner. We are looking forward to advancing this clinical program, along with our strategic partner Otsuka Pharmaceutical, as it marks an important new approach to developing a treatment for dry AMD and other degenerative eye diseases.”

AMD occurs in “dry” and “wet” forms, which together are estimated to affect more than 29 million people worldwide, according to a 2007 Visiongain report. 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.

This Phase 2 trial is a randomized, double-masked, placebo-controlled study of three planned escalating dose levels of ACU-4429 and up to two additional dose levels in subjects with dry

AMD. Patients will receive either ACU-4429 or placebo orally once daily for three months. The trial will be conducted at multiple sites throughout the U.S. and is overseen by an independent Data Monitoring Committee that will approve each escalation in dose. It is anticipated that a minimum of 56 patients with dry AMD will be enrolled.

“Dry AMD is the most common cause of visual loss in the elderly population. Yet, currently, there are no approved therapies to manage dry AMD beyond the anti-oxidants. Our patients are desperately in need of an effective and well tolerated treatment for this devastating condition that can address their early loss of vision before the disease progresses to blindness,” said Quan Dong Nguyen, M.D., M.Sc., Associate Professor of Ophthalmology at the Wilmer Eye Institute, Johns Hopkins University. “I am very encouraged by the preclinical and early clinical data for ACU-4429. Its ability to decrease toxic by-products that have been shown to play a role in the pathogenesis of dry AMD and its easy-to-administer oral dosing, along with a safety profile that thus far has not demonstrated any significant concerns, could bring hope to many patients suffering from dry AMD.”

About the ENVISION Clarity Trial

The ENVISION (Evaluating a Novel VISION treatment for AMD) Clarity Trial is part of Acucela’s 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. Acucela has forged a strategic partnership with Otsuka Pharmaceutical, Co. Ltd. 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.

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