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ACUCELA PRESENTS DRY AMD THERAPY DATA AT ARVO

-- Data from ACU-4429 Demonstrates Potential Treatment of Dry Age-related Macular Degeneration, a Leading Cause of Vision Loss in Adults --

BOTHELL, Wash. (May 12, 2009) – Acucela presented new safety, tolerability and effectiveness data on ACU-4429, an investigational therapy for dry age-related macular degeneration (AMD), at the 2009 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting held this week in Fort Lauderdale, Florida.

Study participants tolerated ACU-4429 well in single-dose tests conducted with healthy volunteers age 55-80, said Ryo Kubota, M.D., Ph.D. founder and CEO of Acucela. Using ERG as a biomarker to measure rod-mediated retinal activity and function, inhibition of the b-wave followed administration of ACU-4429 and exposure to full-field bleach. This effect was seen on the day of dosing. All ERG measurements returned to baseline levels by Day 7 after dosing.

Preclinical data indicated that ACU-4429 slows the rod visual cycle, resulting in decreased accumulation of a toxic byproduct that is the precursor of lipofuscin. Since the chronic accumulation of lipofuscin has been implicated in pathological mechanisms that lead to degenerative retinal diseases, ACU-4429's mechanism of action is an indication of its potential therapeutic effect on these disorders, which include dry AMD and Stargardt's Disease, Kubota said.

Acucela is developing ACU-4429 as a single-dose daily oral treatment for dry AMD, the most common form of the disease. All forms (wet and dry) of AMD affect more than 1.75 million people in the U.S. and are expected to increase to almost 3 million by 2020¹. Currently, there is no approved medicinal therapeutic treatment for dry AMD.

¹ Archives of Ophthalmology 2004; 122:564-572

“Many companies have worked diligently to find a successful treatment for this devastating disease,” Kubota said. “Our early data shows that ACU-4429 has the potential to be a breakthrough treatment.”

Data shows ACU-4429 may potentially slow or halt the progression of dry AMD, Kubota said. ACU-4429 is in Phase I trials, and a Phase II trial is expected to begin later this year.

Acucela also submitted other data at ARVO that demonstrated ACU-4429’s safety profile in multiple animal species, and demonstrated it as a potential inhibitor of isomerization activity in vitro and in vivo for the treatment of dry AMD.

In a separate presentation, Acucela demonstrated the effectiveness of its assays that utilize long-lived, fully-differentiated primary retinal neurons for *in vivo* screening. The screens are referred to as OcuScreen™, which has been developed for drug discovery and detection of retinal toxins.

These abstracts presented at ARVO can be viewed at www.arvo.org.

ACU-4429 is a new therapeutic class of drugs known as “Visual Cycle Modulators,” which are designed to prevent or inhibit generation of by-products that can lead to degenerative eye conditions such as dry-type age-related macular degeneration and Stargardt’s Disease. Data demonstrates the safety profile of ACU-4429 among healthy volunteers and also that ACU-4429 protects photoreceptors from acute light damage and reduces A2E/lipofuscin (considered a major contributor to retinal degenerative conditions) in a genetic animal model.

About Acucela

Acucela Inc. is a clinical-stage biotechnology company focused on developing new drug therapies for blinding eye diseases such as age-related macular degeneration (AMD), Stargardt disease, diabetic retinopathy and retinopathy of prematurity, as well as dry eye. Founded in 2002, Acucela works with proprietary disease-specific assays and technologies to identify and develop compounds that may safely and effectively treat retinal diseases. For more information, please visit www.acucela.com.

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