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## **ACUCELA PRESENTS PRECLINICAL DATA FROM RETINOPATHY STUDY DEMONSTRATING IMPROVEMENT IN RETINAL ABNORMALITIES**

Bothell, WA—April 29, 2008—Acucela Inc., a clinical-stage biotechnology company discovering new drug therapies for eye diseases, today presented preclinical data from a study of a blinding eye disease called retinopathy of prematurity (ROP) demonstrating an improvement in retinal abnormalities following treatment with the company's visual cycle modulation compound. These data were presented today by James D. Akula, Ph.D., Instructor of Ophthalmology at Harvard Medical School at Children's Hospital Boston at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in Fort Lauderdale, Florida.

The preclinical study was conducted in a well-established animal model for ROP (n=46). The animals were given either the visual cycle modulator (a derivative of vitamin A) plus vehicle, or just vehicle and then monitored for 60 days. The drug was shown to be safe and also demonstrated a significant improvement in retinal blood vessels in the drug-treated group compared with the group who received vehicle alone. Blood vessels tend to abnormally spread throughout the retina in ROP, so an improvement in these retinal abnormalities may present a future option that could complement or even replace the antiangiogenic approaches that are currently being evaluated for use in ROP.

"We are excited about the significant improvement in the blood vasculature that we observed in these studies using our visual cycle modulator. The ability of the compound to slow down the visual cycle is consistent with the encouraging data we have demonstrated in a human clinical trial of age-related macular degeneration," stated Ryo Kubota, M.D., Ph.D., president and chief executive officer of Acucela. "There are many greatly unmet medical needs in ophthalmology, including retinopathy of prematurity and age-related macular degeneration (AMD). Based on these data, our visual cycle modulators may be able to treat sight-threatening diseases such as retinopathy of prematurity and proliferative diabetic retinopathy. To our knowledge, this is the first evidence to suggest that VCM may be able to treat other retinal diseases that involve neovascularization that are not accompanied by the accumulation of the retinoid-related toxic byproducts, A2E, which is associated with dry AMD or Stargardt disease. We are excited about our compounds for these indications and believe that our orally-delivered drugs could provide a much more patient-friendly and safer product profile than the options currently being used for neovascular diseases, many of which are administered by injection."

### **About Visual Cycle Modulation and its Impact on Blinding Eye Diseases**

Visual cycle modulation may have the ability to impact multiple blinding eye diseases. Acucela is developing an orally available drug that modulates the visual cycle potentially impacting the processes that can lead to blinding eye diseases such as age-related macular degeneration (AMD), diabetic retinopathy, ROP and Stargardt disease. Acucela expects to commence a Phase 1 clinical trial of a non-retinoid visual cycle modulator for AMD later this quarter.

**About Retinopathy of Prematurity**

ROP is a potentially blinding eye disease that can occur in premature infants and involves abnormal blood vessels growing and spreading throughout the retina, the tissue that lines the back of the eye. These abnormal blood vessels may leak, scarring the retina and pulling it out of position, which may cause detachment of the retina. Retinal detachment is the primary cause of visual impairment and blindness in ROP. There are approximately 15,000 annual cases of ROP in the U.S. of which approximately 10 percent are considered severe. There is currently no approved treatment for ROP.

**About Acucela**

Acucela Inc. is focused on developing new drug therapies for eye diseases, and particularly neurodegenerative retinal diseases such as macular degeneration. The company has proprietary disease-specific assays and technologies to identify and develop compounds that may safely and effectively treat retinal diseases and injuries. The company's novel approaches have significant therapeutic potential to treat retinal diseases such as Age-related Macular Degeneration (AMD) and Stargardt disease, which affect 50 million people worldwide. The Bothell-based, privately-held, biotechnology company was founded in 2002. For more information, please visit <http://www.acucela.com>.

**Forward-Looking Statement**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements include statements regarding product development. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Acucela undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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