Phase 1/2 Uveitis Clinical Trial Evaluating DSP-Visulex™ Now Open for Enrollment

Salt Lake City, UT- December 2, 2014 – Aciont Inc., a specialty biopharmaceutical company endeavoring to become a leader in non-invasive drug delivery treatments for sight threatening diseases, announced that its DSPV-201 clinical study is open for enrollment to patients at study sites located in the United States. Currently, both the Ocular Immunology and Uveitis Foundation at Massachusetts Eye Research and Surgery Institution (MERSI) and the Retina and Uveitis Consultants of Texas (RUCT) are open for enrollment.

“Aciont is honored to have world renowned uveitis experts involved with the execution of our clinical trial,” said John Higuchi, Aciont’s chief executive officer. Dr. C. Stephen Foster and Dr. David Scales, respectively, are the principal investigators of the DSPV-201 study at these sites and several other clinical sites are in process to initiate their enrollments by the end of the year including the Moran Eye Center of the University of Utah. Dr. Albert T. Vitale is the principal investigator of the DSPV-201 study at the Moran and he is co-author with Dr. Foster, of the definitive text on the subject, *Diagnosis and Treatment of Uveitis*.

“Opening this pivotal DSPV-201 study under an open IND is a crucial milestone for us to pursue non-infectious anterior uveitis as our first indication for DSP-Visulex in the U.S.," said Dr. Balbir Brar, Aciont’s senior vice president of research and development. “DSP-Visulex may replace the frequent dosing of corticosteroid eye drops, and reduce the need for systemic and ocular injections of corticosteroids for many other potential intraocular inflammation disease indications” Dr. Brar added.

The objective of this trial is to determine the efficacy, safety, and tolerability of DSP-Visulex after repeated-dose administration in patients with acute anterior uveitis. The study is titled "A randomized, parallel group, double-masked, active-controlled Phase 1/2 clinical trial to evaluate the efficacy and safety of dexamethasone sodium phosphate (DSP) Visulex system for the treatment of non-infectious, anterior uveitis.” Approximately forty-five patients will be randomized to one of three treatment groups: Two groups of highly potent DSP-Visulex formulations, each with placebo eye drops, are being compared to prednisolone acetate 1% eye drops with vehicle-Visulex. The study's primary endpoint is the change from baseline in anterior chamber cell (ACC) grade at Days 8, 15, and 29.

“The feedback from ophthalmologists on our Visulex platform has been very positive. The doctors have found that it is very straight forward and easy to place on human eyes. It has a very thorough design and we have collaborated extensively with optometrists, ophthalmologists, pharmaceutical scientists, and engineers to create this drug delivery platform that will fit the majority of the population’s eyes,” said Dr. Kongnara Papangkorn, vice president of product development. "With our preclinical data on both safety and efficacy, Aciont is confident that DSP-Visulex will be proven beneficial to patients,” Dr. Papangkorn added.

About the DSPV-201 Uveitis Clinical Study

DSPV-201 is a randomized, parallel group, double-masked, active-controlled Phase 1/2 clinical trial of dexamethasone sodium phosphate Visulex system (DSP-Visulex) for the treatment of non-infectious, anterior uveitis. More details about DSP-Visulex clinical study (DSPV-201) can be found at www.clinicaltrials.gov. The study described is currently being funded in large part by NIH Award Number R44EY014772-05 from the National Eye Institute. Non-infectious, anterior uveitis is intraocular inflammation of the uveal structures anterior to the middle of the vitreous cavity. It is the predominant type of uveitis and involves inflammation of the front of the eye including iris and ciliary body.

Non-infectious anterior uveitis is characterized by eye pain, blurred vision, photophobia, floaters, and redness. This disease may be associated with ocular trauma as well as many systemic diseases, including juvenile idiopathic arthritis, ankylosing spondylitis, reactive arthritis, and sarcoidosis. Treatment for anterior uveitis usually involves topical corticosteroids and cycloplegic eye drops and occasionally oral steroids or nonsteroidal anti-inflammatory drugs (NSAIDs) may be prescribed. The objectives of the treatment are to preserve visual acuity, relieve ocular pain, eliminate ocular inflammation, prevent formation of synechiae, and manage intraocular pressure. If left untreated or under treated, uveitis can cause permanent damage and visual loss due to the development of glaucoma, cataract, or retinal edema.

About DSP-Visulex

The Visulex system is a non-invasive drug delivery platform for treating sight threatening diseases. Specifically, Visulex-P delivers small drug molecules transsclerally by passive diffusion through the limbal sclera into the interior of the eye. Based upon an experimental autoimmune uveitis (EAU) rabbit model, a model to evaluate treatments for intermediate and posterior uveitis, the Visulex-P can deliver therapeutically relevant amounts of dexamethasone sodium phosphate (DSP) to the rabbit eye tissues within 5 minutes.

DSP incorporated into the Visulex-P, called DSP-Visulex, is intended globally for the treatment of non-infectious uveitis including pan-, anterior-, intermediate-, and posterior-uveitis. DSP-Visulex intends to address problems of existing corticosteroid treatment options for non-infectious uveitis. These include eliminating the need for frequent dosing of eye drops, reducing the systemic side effects of corticosteroid oral therapy and avoiding the serious risks associated with intravitreal and periocular injections.

About Aciont Inc.

Aciont Inc. is a specialty biopharmaceutical company endeavoring to become the world leader in commercializing non-invasive therapeutics for sight threatening diseases including severe uveitis, diabetic macular edema and age-related macular degeneration. Aciont has two technology platforms: Visulex-P, topical passive diffusion-based; and Visulex-I, iontophoretic-based, both of which can be combined with propriety pharmaceutical formulations to optimize delivery and residence time of the drug inside the target eye tissues. Aciont's goal is to provide ophthalmologists substantially greater freedom in treating and/or preventing acute or chronic eye diseases through optimal drug dosing and improved patient/physician compliance. Aciont is located in Salt Lake City, Utah. More detailed information can be found at www.aciont.com.