

## **Clearside Biomedical, Inc. Enrolls First Patient in Phase 3 Clinical Trial of CLS-TA Using Suprachoroidal Drug Administration**

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*First Patient Randomized in Six-Month Efficacy Trial for the Treatment of Macular Edema Associated with Non-Infectious Uveitis*

**Alpharetta, GA (December 7, 2015)** - Clearside Biomedical, Inc., a clinical-stage biopharmaceutical company developing innovative first-in-class drug therapies to treat blinding diseases of the eye, today announced that the first patient was enrolled in Clearside's Phase 3 clinical trial, Peachtree, of CLS-TA, Clearside's proprietary form of triamcinolone acetonide (TA), using suprachoroidal space (SCS™) drug administration for the treatment of macular edema associated with non-infectious uveitis.

"The enrollment of our first patient and the advancement of CLS-TA into a pivotal trial for uveitis is a milestone for our organization and puts Clearside on a potential course to file our first NDA in 2017," said Daniel H. White, CEO and President of Clearside. "We now have enrolled more than 70 patients in five clinical trials using SCS™ drug administration studying potential treatments for blinding conditions like uveitis, retinal vein occlusion (RVO), wet age-related macular degeneration (AMD) and diabetic macular edema (DME)."

The Peachtree trial is a randomized, masked, sham-controlled trial to assess the efficacy and safety of 4 mg of CLS-TA administered via SCS™ injection in subjects with macular edema associated with non-infectious uveitis. Patients will be randomized to receive two unilateral SCS™ injections of CLS-TA or two unilateral sham procedures approximately 12 weeks apart. The clinical endpoint in the trial is the proportion of patients with a change in baseline of at least 15 letters in best corrected visual acuity (BCVA) as measured using the Early Treatment of Diabetic Retinopathy Study (ETDRS) scale at 24 weeks. There will be several secondary efficacy and safety endpoints that will also be evaluated. Clearside anticipates total enrollment of approximately 150 patients in the two-arm, six-month efficacy trial, across approximately 50 clinical sites.

This treatment for uveitis is part of Clearside's strategy of developing drug treatments for unmet or underserved blinding eye diseases where the pathologies dominantly originate or manifest in the choroid or retina.

### **About the Suprachoroidal Space (SCS™)**

The suprachoroidal space is no wider than 30 µm and is located between the choroid and the sclera. The SCS™ extends from the anterior (front) portion of the eye near the ciliary body to the posterior of the eye near the optic nerve. The SCS™ provides a potential route of access from the anterior region of the eye to treat diseases of the back-of-the-eye like uveitis, RVO, wet AMD and DME.

### **About Uveitis**

Uveitis is [inflammation](#) inside the eye, specifically affecting one or more of the three parts of the eye that make up the [uvea](#): the [iris](#) (the colored part of the eye); the [ciliary body](#) (behind the iris, responsible for manufacturing the fluid inside the eye); and the [choroid](#) (the vascular lining tissue underneath the [retina](#)). Uveitis is one of the most frequent causes of blindness in the developed world. Based on prevalence data published in the journal *Ophthalmology* in 2004 and United States census data for 2010, it is estimated approximately 350,000 individuals in the United States suffer from some form of uveitis. Typically diagnosed in individuals between the ages of 20 and 50, uveitis can occur in one or both eyes and accounts for approximately 10% of cases of blindness in the United States, according to a study published in

*Journal of Ophthalmology*. Uveitis can be either infectious or non-infectious. Non-infectious uveitis accounts for approximately 80% of all uveitis cases. Macular edema related to uveitis is the predominant cause of blindness or visual impairment among patients with uveitis, accounting for approximately 30% of cases of blindness in uveitis patients. Because uveitis can become chronic or recurrent if not adequately treated, some patients may become refractory, or unresponsive, to treatment, leading to irreversible blindness.

### **About Clearside Biomedical, Inc.**

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a clinical-stage biopharmaceutical company developing innovative first-in-class drug therapies to treat blinding diseases of the eye using Clearside's proprietary microinjector to reach diseased tissue through the SCS™. Clearside holds intellectual property protecting the delivery of drugs of any type through the SCS™ to reach the back of the eye. Visit [www.clearsidebio.com](http://www.clearsidebio.com) for more information.

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