

Clearside Biomedical, Inc. Announces Positive Topline Data from Phase 2 Clinical Trial for the Treatment of Macular Edema Associated with Non-Infectious Uveitis

January 5, 2016 2:11 AM ET

Clinical Trial Achieves Statistical Significance on Primary Efficacy Endpoint

Alpharetta, GA (January 5, 2016) - Clearside Biomedical, Inc., a late-stage clinical biopharmaceutical company developing innovative first-in-class drug therapies to treat blinding diseases of the eye, today announced positive results from the company's Phase 2 clinical trial of CLS-TA, Clearside's proprietary form of triamcinolone acetonide, using suprachoroidal space (SCS™) drug administration for the treatment of macular edema associated with non-infectious uveitis.

The trial, referred to as the Dogwood trial, evaluated the safety and efficacy of CLS-TA in 22 patients with macular edema associated with non-infectious uveitis. In the trial, administration of CLS-TA resulted in a statistically significant mean change from baseline in central subfield thickness at eight weeks after one single treatment, which was the primary endpoint ($p=0.0018$). Statistical significance was also achieved in the mean increase from baseline in best-corrected visual acuity ($p=0.0004$), a secondary endpoint. There were no treatment-related serious adverse events reported in the trial, including no reported steroid-related increases in intraocular pressure (IOP), which is common in intravitreal and periocular drug delivery of corticosteroids. Clearside plans on submitting the full data set for presentation at an upcoming medical meeting.

"The data from this clinical trial continue to provide support for the approach to treatment of certain blinding eye diseases through SCS™ administration and the potential for an effective and safe option for the treatment of uveitis using CLS-TA, Clearside's proprietary triamcinolone acetonide formulation," said Daniel H. White, CEO and President of Clearside.

The Dogwood trial was the first masked, randomized clinical trial conducted in which drug was administered through the SCS™. This U.S., multi-center trial randomly assigned patients in a 4:1 ratio to receive a single injection of CLS-TA, 4 mg/100 µL or CLS-TA, 0.8 mg/100 µL. Subjects were treated at Day 1 and were monitored for safety and efficacy for eight weeks following their SCS™ injection.

Clearside Biomedical has a portfolio of clinical and pre-clinical programs using drug administration through the SCS™ to provide a route of access to treat diseases of the back-of-the-eye like uveitis, retinal vein occlusion (RVO), wet age-related macular degeneration (AMD) and diabetic macular edema (DME). Clearside has enrolled its first patients in a Phase 3 clinical trial (Peachtree) for the treatment of patients with macular edema associated with non-infectious uveitis; completed enrollment of a Phase 2 clinical trial (Tanzanite) assessing the efficacy and safety of CLS-TA used concomitantly with an intravitreal injection of a VEGF inhibitor in patients with macular edema associated with RVO; and initiated IND-enabling studies for the treatment of AMD.

About Uveitis

Uveitis is [inflammation](#) inside the eye and is classified anatomically as anterior, intermediate, posterior or pan-uveitis, according to the primary site of inflammation. Each of these categories, however, encompasses a number of conditions that can be characterized further along other dimensions including: onset, duration, course and etiology. 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 that 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 late-stage clinical biopharmaceutical company developing innovative first-in-class drug therapies to treat blinding diseases of the eye using Clearside's proprietary SCS™ 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 for more information.

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