

# Data From Clearside Biomedical's Pivotal Phase 3 PEACHTREE Clinical Trial in Macular Edema Associated with Non-Infectious Uveitis to be Presented at the Retina Society 51st Annual Scientific Meeting

September 13, 2018

ALPHARETTA, Ga., Sept. 13, 2018 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases, announced today that data from PEACHTREE, its pivotal Phase 3 trial of suprachoroidal CLS-TA in patients with macular edema associated with non-infectious uveitis, will be presented by Rahul N. Khurana, MD, an investigator for PEACHTREE, Partner at Northern California Retina Vitreous Associates, and Clinical Associate Professor in Ophthalmology at UCSF Medical Center, during a scientific session on Inflammation at the Retina Society 51<sup>st</sup> Annual Scientific Meeting in San Francisco, California.

Dr. Khurana's presentation, titled "Suprachoroidally Injected CLS-TA Improves Visual Acuity and Macular Edema in Non-infectious Uveitis: Results of the Phase 3 PEACHTREE Study," is scheduled for Friday, September 14 at 3:55 p.m. Pacific Time.

"We expect to submit an NDA for suprachoroidal CLS-TA to treat macular edema associated with non-infectious uveitis to the FDA by the end of 2018," said Clearside's Chief Executive Officer and President, Daniel H. White. "Our confidence continues to grow in the potential of suprachoroidal CLS-TA, if approved, to become an important new treatment option for retinal and choroidal diseases like macular edema associated with non-infectious uveitis, and we are excited to share the PEACHTREE data with researchers and clinicians at this important forum."

## **About Suprachoroidal CLS-TA**

Suprachoroidal CLS-TA, Clearside's first investigational treatment, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye via the suprachoroidal space, or SCS<sup>TM</sup>, which is the space located between the choroid and the outer protective layer of the eye known as the sclera. Clearside's proprietary suprachoroidal treatment approach is designed to enable rapid dispersion of a high amount of medicine to the back of the eye so that adequate medicine reaches and stays at the site of disease and has potential to act longer. This approach has potential to provide efficacy advantages and require fewer treatments and office visits while minimizing harm to the surrounding healthy parts of the eye.

Suprachoroidal CLS-TA, used either alone or together with an intravitreal anti-VEGF agent, is being studied as part of Clearside's pipeline of treatments for unmet or underserved sight-threatening eye diseases that manifest in the retina and the choroid.

# **About PEACHTREE**

PEACHTREE, a randomized, masked, sham-controlled Phase 3 trial, enrolled 160 patients with macular edema associated with non-infectious uveitis.

In the PEACHTREE trial, 47% of patients in the treatment arm who received suprachoroidal CLS-TA every 12 weeks gained at least 15 letters in best corrected visual acuity, as measured using the Early Treatment of Diabetic Retinopathy Study scale, from baseline at week 24, compared to 16% of patients in the control arm who underwent a sham procedure. This improvement, which was the primary endpoint of the trial, was statistically significant (p < 0.001). All key secondary endpoints of the PEACHTREE trial were also achieved.

#### **About Uveitis**

Uveitis, a set of inflammatory conditions affecting the eye, is one the world's leading causes of blindness. Uveitis occurs in about 350,000 patients in the United States and is typically found in both eyes. Macular edema is the build-up of fluid in the macula, an area in the center of the retina responsible for sharp, straight-ahead vision. Fluid buildup causes the macula to swell and thicken, which distorts vision. Macular edema occurs in approximately one-third of all non-infectious uveitis cases and is a major contributor to vision impairment and vision loss in these patients.

### **About Clearside**

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases. Clearside's proprietary suprachoroidal treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. The company's unique platform for eye disease treatments is inherently flexible and intended to work with established medicines, new formulations of medicines, as well as future innovations. Clearside's pipeline includes advanced and pre-clinical product candidates in diseases where macular edema is a common complication, including uveitis, retinal vein occlusion ("RVO") and diabetic macular edema ("DME"). Clearside's most advanced program is in non-infectious uveitis and it expects to submit a New Drug Application to the U.S. Food and Drug Administration for use of suprachoroidal CLS-TA for the treatment of macular edema associated with non-infectious uveitis by the end of 2018. The company is also conducting two ongoing Phase 3 trials of suprachoroidal CLS-TA with an intravitreal anti-VEGF agent in patients with RVO. In addition, Clearside recently announced positive topline results from a Phase 2 clinical trial of suprachoroidal CLS-TA used with EYLEA® (aflibercept) in patients with DME, and is continuing to analyze additional data from the trial as it becomes available. Clearside is headquartered in Alpharetta, GA. For more information, please visit <a href="http://www.clearsidebio.com">http://www.clearsidebio.com</a>. Follow @clearsidebio on Twitter and Linkedin.

## **Cautionary Note Regarding Forward-Looking Statements**

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe", "expect", "may", "plan",

"potential", "will", and similar expressions, and are based on Clearside's current beliefs and expectations. These forward-looking statements include expectations regarding the clinical development of Clearside's product candidates, the potential attributes and benefits of Clearside's product candidates, and the timing of a potential submission of an NDA with the FDA. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Clearside's reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 16, 2018, and Clearside's other Periodic Reports filed with the SEC. Any forward-looking statements speak only as of the date of this press release and are based on information available to Clearside as of the date of this release, and Clearside assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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Source: Clearside Biomedical, Inc.