Presentation of Additional Analyses of Clearside's PEACHTREE Clinical Trial Data Further Supports Potential of XIPERE™ in Treating Uveitic Macular Edema

October 29, 2018

ALPHARETTA, Ga., Oct. 29, 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 additional data from PEACHTREE, the company's pivotal Phase 3 trial of XIPERE™ (formerly "suprachoroidal CLS-TA") in patients with uveitic macular edema, were presented at the American Academy of Ophthalmology ("AAO") 2018 Annual Meeting by Rahul N. Khurana, MD, Vitreoretinal Surgeon at Northern California Retina Vitreous Associates, Clinical Associate Professor in Ophthalmology at UCSF Medical Center, and a Principal Investigator for PEACHTREE.

At the meeting, Dr. Khurana shared XIPERE's efficacy data in resolving uveitic inflammation for the first time at a scientific congress. Dr. Khurana also presented new analyses of resolution of clinically significant vitreous haze, as well as the mean change from baseline in best corrected visual acuity ("BCVA") in patients with uveitis in each anatomical location, providing further support for the clinical profile of XIPERE in the potential treatment of uveitic macular edema.

Resolution of Signs of Uveitis

In the PEACHTREE trial, at week 24, 40.9% of patients with baseline scores of 2+ vitreous haze, based on the Standardization of Uveitis Nomenclature ("SUN") scale, experienced resolution in the XIPERE arm, compared to 0% of patients in the control arm who underwent a sham procedure. Additionally, in the XIPERE arm, 68% of patients with any baseline level of vitreous haze, 72% of patients with anterior chamber cell inflammation and 74% of patients with anterior chamber flare had their inflammation resolve, compared to 23%, 17% and 20%, respectively, of patients in the control arm. Resolution was defined as achieving a score of zero on the applicable SUN scale, implying no measureable inflammation was present.

"The PEACHTREE trial was the first pivotal Phase 3 clinical trial to demonstrate improvement in vision for patients with uveitic macular edema, and patients experiencing resolution of uveitis is an important outcome for uveitis specialists and for their patients," commented Dr. Khurana. "These additional data add to my confidence that XIPERE holds promise for my patients with uveitic macular edema."

Change in BCVA Across Anatomical Locations of Uveitis

Dr. Khurana also presented an analysis of the mean change in BCVA, from baseline at week 24 from each anatomical location of uveitis: Anterior, Intermediate, Posterior and Panuveitis.

Mean Change From Baseline in BCVA at Week 24 by Anatomical Location

	XIPERE Arm (ETDRS Letters)	**Control Arm (ETDRS Letters)**
Anterior Uveitis	14.4	2.9
Intermediate Uveitis	13.4	6.7
Posterior Uveitis	15.6	1.4
Panuveitis	12.0	-1.6

"Unlike current therapies, which have shown efficacy in certain locations of uveitis, such as anterior or posterior segment uveitis, patients treated with XIPERE in the PEACHTREE trial achieved visual improvement across all anatomical locations of uveitis. This serves to further differentiate the impressive clinical profile of XIPERE," said Dr. Khurana.

About XIPERE

XIPERE, 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®, 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 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.

XIPERE, 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. Clearside expects to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for XIPERE for the treatment of uveitic macular edema by the end of 2018.

About PEACHTREE

PEACHTREE, a randomized, masked, sham-controlled Phase 3 trial, enrolled 160 patients with macular edema associated with non-infectious uveitis, comparing XIPERE dosed every 12 weeks to sham control.

The PEACHTREE trial met its primary endpoint at 24 weeks, with 47% of patients in the XIPERE arm gaining at least 15 ETDRS letters in BCVA from baseline, compared to 16% of patients in the sham control arm ($p<0.001$). All key secondary and additional 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 NDA to the FDA for XIPERE for the treatment of uveitic macular edema by the end of 2018. The company is also conducting two ongoing Phase 3 trials of XIPERE 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 XIPERE used with EYLEA® (aflibercept) in patients with DME, and is continuing to analyze additional data from the trial. Clearside is headquartered in Alpharetta, GA. For more information, please visit http://www.clearsidebio.com. 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.

Contacts:

Stephen Kilmer
Investor Relations
(678) 430-8206
stephen.kilmer@clearsidebio.com

Charles Deignan
Chief Financial Officer
(678) 270-4005
charlie.deignan@clearsidebio.com

CLEARSIDE™ BIOMEDICAL

Source: Clearside Biomedical, Inc.