Clearside Biomedical Suprachoroidal Injection Platform Featured in Multiple Presentations at the American Academy of Ophthalmology (AAO) 2019 Annual Meeting

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XIPERE™ presentations continue to demonstrate the potential value to treat uveitis patients

ALPHARETTA, Ga., Oct. 17, 2019 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (Nasdaq:CLSD), a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases, announced today that multiple oral presentations on Clearside's pipeline and proprietary SCS Microinjector™ targeting the suprachoroidal space were given at the American Academy of Ophthalmology (AAO) 2019 Annual Meeting.

"With multiple presentations at AAO this week featuring Clearside's suprachoroidal injection platform, we are encouraged by the physician support and enhanced understanding of the value of our treatment approach," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer. "The potential for in-office gene therapy delivery via our SCS Microinjector continues to generate high interest, while further analysis of XIPERE™ demonstrates its potential value to treat uveitis patients, as well as the opportunity to explore treatment options in diabetic macular edema. In addition, our recent licensing partnerships with Aura Biosciences and REGENXBIO have significantly expanded our presence into additional therapeutic areas including ocular oncology and AAV anti-VEGF gene therapy for wet AMD and diabetic retinopathy."

Title: ***Suprachoroidal Delivery for Ocular Gene Therapy: Nonclinical Experiments Evaluating Non-viral DNA Nanoparticles***

Author: Christine N. Kay, M.D., Vitreoretinal Associates, Gainesville, FL

Summary: As background information, Dr. Kay discussed the fact that inherited retinal diseases represent some of the most challenging diseases that ophthalmologists encounter. They cause progressive, relentless vision loss due to changes in genes critical to the survival of photoreceptors and retinal pigment epithelial (RPE) cells; delivery of therapeutics to these cells is very challenging. Dr. Kay's presentation described the nonclinical studies for the use of gene therapy via suprachoroidal injection designed to evaluate the safety, tolerability, and retinal cell transfection following suprachoroidal injection of DNA nanoparticles (DNPs). In the studies, a luciferase assay was used to study gene expression in the animal models via suprachoroidal administration of DNA nanoparticles (DNPs). Luciferase activity was observed in the retina and RPE and choroid of all eyes that received suprachoroidal injection of DNPs. In rabbits, suprachoroidal injection of luciferase DNPs produced activity comparable to that seen from subretinal injections of luciferase DNPs. SCS injections of DNPs were generally well-tolerated across both rabbits and non-human primates, and no significant abnormalities were observed on ophthalmic exams. DNPs can also transfer large genes at potentially higher doses without the risks of subretinal surgery which may allow for gene therapy in the most common inherited retinal diseases (IRDs) such as Stargardt disease and Usher syndrome.

Title: ***A Subgroup Analysis of Subjects Diagnosed with Anterior Uveitis from the Phase 3 PEACHTREE Clinical Trial***

Author: Ashleigh L. Levison, M.D., Colorado Retina Associates

Summary: Dr. Levison presented a post hoc subgroup analysis from the Phase 3 trial PEACHTREE study focusing on the patients with anterior uveitis. In the trial, patients with uveitis from any anatomic location were enrolled, of which 25.6% had anterior uveitis. At week 24, the anterior uveitis patients in the CLS-TA group improved meaningfully. Specifically, best corrected visual acuity improved by 14.4 letters compared to 2.9 letters in the control group. Dr. Levison concluded that suprachoroidal delivery of CLS-TA demonstrated improvements in visual acuity, anatomic outcomes and inflammation in anterior uveitis patients.

Title: ***Suprachoroidal Triamcinolone Acetonide Suspension (CLS-TA) and Intraocular Pressure: Results from the Phase 3 PEACHTREE Clinical Trial for Uveitis***

Author: Steven Yeh, M.D., M. Louise Simpson Associate Professor of Ophthalmology; Faculty Fellow, Emory Global Health Institute, Emory Eye Center

Summary: Dr. Yeh presented the results of PEACHTREE focusing on intraocular pressure (IOP). With respect to elevated IOP-related adverse events (AEs), the rate was 11.5% in the CLS-TA treatment group (n=11/96) compared to 15.6% in the control group (n=10/64). Rescue medications were required in 72% (n=46/64) of the patients in the control group and only 13.5% (n=13/96) in the CLS-TA group. Of these, intravitreal and periocular corticosteroids were most commonly prescribed. Clinically relevant IOP endpoints were evaluated through week 24. IOP ≥ 30mmHg was observed in only 4.8% of CLS-TA treated eyes (n=4/83) that did not receive rescue medication compared to 10.9% of control eyes (n=5/46) that received rescue. Similarly, IOP lowering medications were used in fewer eyes treated only with CLS-TA (7.2%; n=6/83) compared to the control eyes receiving rescue treatment (13%; n=6/46).

Title: ***Suprachoroidal CLS-TA Plus Aflibercept Compared with Aflibercept Monotherapy for DME: Selected Secondary Results of the Randomized Phase 2 TYBEE Trial***

Author: Michael S. Ip, M.D., The Doheny Image Reading Center, Doheny Eye Institute, University of California – Los Angeles

Summary: In an ePoster presentation, Dr. Ip and his team evaluated secondary results from Clearside's Phase 2, double-masked, 6-Month TYBEE clinical trial in patients with Diabetic Macular Edema (DME). The trial evaluated combination aflibercept and suprachoroidal CLS-TA treatment compared to aflibercept monotherapy at Week 24. Dr. Ip addressed the fact that "real world" outcomes are worse than those seen in clinical trials likely due to poor patient compliance to receive their injections. Meaningfully, the results from TYBEE demonstrate that fewer treatment visits were needed in the combination arm (2.8) compared to aflibercept monotherapy (4.7), suggesting the potential to address treatment burden. The trial demonstrated a similar mean change in best corrected visual acuity (BCVA) between the combination arm (12.3) versus aflibercept monotherapy (13.5) (p=.66). In the trial, changes in disorganization of the retinal inner layers (DRIL) were similar in both arms and DRIL could be a reasonable biomarker to evaluate in future DME clinical trials.

At the Retina Subspecialty Day, Albert T. Vitale, M.D., Professor Ophthalmology/Visual Sciences, University of Utah Health, John A. Moran Eye Center, highlighted the results from Clearside's Phase 3 PEACHTREE clinical trial during his presentation entitled, *"Treating Uveitic Edema".*

In addition, Debra Goldstein M.D., Director of Uveitis in the Department of Ophthalmology at Northwestern University, presented "Microneedle Delivery" during a symposium, "Delivery of Therapeutics to the Posterior Ocular Segment". She reviewed the progression of suprachoroidal drug delivery from preclinical to clinical studies, culminating with Clearside's Phase 3 PEACHTREE trial. She also highlighted potential applications of suprachoroidal delivery.

These presentations will be available on Clearside's website in the Publications section under Programs (https://www.clearsidebio.com/publications.htm).

About XIPERE™

XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye for the treatment of macular edema associated with uveitis. Clearside's patented technology is designed to deliver drug to the suprachoroidal space located between the choroid and the outer protective layer of the eye, known as the sclera. Suprachoroidal injection enables the rapid and adequate dispersion of medicine to the back of the eye, offering the potential for the medicine to act longer and minimize harm to the surrounding healthy parts of the eye, thus potentially providing advantageous and sustained efficacy with a favorable safety profile.

About PEACHTREE

PEACHTREE, a randomized, masked, sham-controlled Phase 3 trial, enrolled 160 patients with macular edema associated with non-infectious uveitis, and compared XIPERE dosed every 12 weeks to sham control. The PEACHTREE trial met its primary endpoint, with 47% of patients in the XIPERE arm gaining at least 15 letters in best corrected visual acuity from baseline at week 24, compared to 16% of patients in the sham control arm ($p<0.001$), using standardized Early Treatment of Diabetic Retinopathy Study (ETDRS) visual acuity testing. All key secondary and additional endpoints of the PEACHTREE trial were also achieved.

About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases. Clearside's proprietary SCS Microinjector™ targeting the suprachoroidal space (SCS) offers unique access to the macula, retina and choroid where sight-threatening disease often occurs. The Company's SCS injection platform is an inherently flexible, in-office, non-surgical procedure, intended to provide targeted delivery to the site of disease and to work with both established and new formulations of medications, as well as future therapeutic innovations such as gene therapy. For more information, please visit www.clearsidebio.com.

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 statements regarding the potential to bring XIPERE to market for uveitis patients, opportunities for expanding Clearside's internal pipeline, and the potential benefits of XIPERE and the SCS injection platform. 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, 2018, filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2019, Clearside's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 8, 2019, 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.

Investor and Media Contacts:

Jenny Kobin
Remy Bernarda
ir@clearsidebio.com
(678) 430-8206

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