Clearside Biomedical's Suprachoroidal Injection Platform Featured in Multiple Oral Presentations at 42nd Annual Meeting of The Macula Society

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- Presentations highlighted data analyses across multiple disease states -

- New, nonclinical data indicates potential for suprachoroidal administration of gene-based therapies -

ALPHARETTA, Ga., Feb. 19, 2019 (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 multiple oral presentations were given at the 42nd Annual Macula Society Meeting held February 13-16, 2019 in Bonita Springs, Florida. The four scientific presentations reviewed clinical and nonclinical data analyses of Clearside programs in multiple disease states, including macular edema associated with uveitis and diabetic macular edema (DME), as well as gene therapy.

Dr. Steven Yeh, Associate Professor, Emory Eye Center, stated, "Suprachoroidal injections are a novel drug delivery approach with high selectivity for the retina and choroid. The compilation of data presented this week continues to demonstrate the potential advantages this therapeutic platform may bring to patients suffering from a variety of blinding eye diseases."

"With the submission of our new drug application for XIPERE™, we are working to build awareness of the broad potential of our suprachoroidal injection platform within the physician community. While our first potential commercial indication is in uveitic macular edema, we plan to expand to other areas within uveitis, diabetic macular edema, and gene therapy. We are grateful for the support of these investigators who presented the data demonstrating the potential of our platform in multiple settings," added Thomas A. Ciulla, M.D., MBA, Clearside Chief Medical Officer.

Presentation:
Dr. Szilard Kiss, Director of Clinical Research, Associate Professor of Ophthalmology, Weill Cornell Medical College presented nonclinical data providing preliminary evidence of the potential for suprachoroidal administration of gene-based therapies.

Title: *A new approach to ocular gene therapy: Evaluation of suprachoroidal administration of non-viral DNA nanoparticles in a rabbit model*

Summary:
Suprachoroidal administration of ellipsoid luciferase non-viral DNA nanoparticles ("DNPs") produced activity that was comparable to that seen from subretinal injections, and significantly greater than that seen from the negative control or untreated eyes. Suprachoroidally injected DNPs were well tolerated, showed luciferase expression/activity in the choroid and retina of rabbit eyes, and provided preliminary evidence of the potential for suprachoroidal administration of gene-based therapies. Specifically, suprachoroidal administration may offer targeted delivery of gene therapies without risks of vitrectomy and subretinal administration.

Presentation:
Dr. Charles Wykoff, Physician, Surgeon, Co-Director of Greater Houston Retina Research Center, & Clinical Assistant Professor of Ophthalmology, Retina Consultants of Houston presented the results of the Phase 2 TYBEE trial in diabetic macular edema.

Title: *Suprachoroidal CLS-TA Plus Aflibercept Compared to Aflibercept Monotherapy for Diabetic Macular Edema: Results of the Randomized Phase 2 TYBEE Trial*

Summary:
Therapy of suprachoroidal CLS-TA and aflibercept showed similar visual and anatomic outcomes compared to aflibercept monotherapy for the treatment of DME. Combination dosing was associated with a meaningful reduction in treatment burden. Ocular adverse events were low for both arms.

Presentation:
Dr. Steven Yeh, Associate Professor, Emory Eye Center reviewed results of XIPERE from the Phase 3 PEACHTREE study.

Title: *Suprachoroidal CLS-TA Improves Visual Acuity and Macular Edema in Noninfectious Uveitis: Results of the Phase 3 PEACHTREE Study*

Summary:
In this pivotal, 6-month, Phase 3 trial in subjects with uveitic macular edema of any anatomic location, suprachoroidal injection of CLS-TA met its primary endpoint (47% of subjects gaining 3-lines or greater in BCVA) when compared to sham control, while also demonstrating an acceptable safety profile.

Presentation:
Dr. Seenu Hariprasad, Chief, Vitreoretinal Service, University of Chicago presented a combined analysis on the results from the AZALEA, DOGWOOD, and PEACHTREE studies in macular edema.

Title: *Suprachoroidally Injected CLS-TA Results in Rapid and Sustained Resolution of Macular Edema in a Majority of Uveitis Patients: Results of the AZALEA, DOGWOOD, and PEACHTREE Studies*

Summary:
These clinical trials consistently demonstrated that treatment of uveitic macular edema with suprachoroidally injected CLS-TA was associated with rapid improvement in macular edema that was sustained through study completion. The suprachoroidal approach offers the potential to more precisely target chorioretinal tissues and facilitate the treatment of visual loss in patients with uveitic macular edema.

These presentations are available on Clearside's website in the Science section under Programs (http://www.clearsidebio.com/programs.htm#SCIENCE).

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 via suprachoroidal injection 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. A New Drug Application ("NDA") was submitted to the U.S. Food and Drug Administration ("FDA") in December 2018 for XIPERE, and, if approved, XIPERE will be the first therapy indicated for macular edema associated with uveitis.

About Clearside Biomedical

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 such as gene therapy. Clearside is headquartered in Alpharetta, GA. For more information, please visit http://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 expectations regarding the clinical development of Clearside's product candidates, the potential attributes and benefits of Clearside's product candidates, and the potential approval and commercialization of XIPERE in the United States. 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 U.S. Securities and Exchange Commission ("SEC") on March 16, 2018, Clearside's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 8, 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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