Clearside Biomedical Featured at Multiple European Scientific Retinal Congresses

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ALPHARETTA, Ga., Sept. 19, 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 numerous presentations were given at three scientific congresses in Europe over the past two weeks.

"Clearside was well represented at three prominent medical meetings in Europe with featured presentations on gene therapy delivery, additional analysis of our XIPERE™ clinical programs, and the unmet need in diabetic macular edema," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer. "We were pleased to be a part of the numerous discussions around gene therapy and the potential for suprachoroidal delivery to enhance treatment options in this area. The uveitis and retina communities are increasingly supportive of our efforts to bring XIPERE to market, if approved, for their uveitis patients, as well as our progress in gene therapy, small molecules, and delivery of ocular oncology therapies. We look forward to working closely with our partners and seeking indications internally to expand our pipeline."

Conference: Ophthalmology Futures Forum, Retina 2019, September 3, 2019, Paris, France

Session:	Safety, Vectors and Routes of Delivery for Stem Cells and Gene Therapy
Summary:	Clearside's Dr. Thomas Ciulla joined other academic and industry experts in the discussion of stem cells and gene therapy. The session reviewed novel endpoints, immune responses, and delivery methods for gene therapy, highlighting suprachoroidal administration and its potential for enhanced patient access to office-based gene therapy, as well as the potential for enhanced delivery to the retina.

Conference: European Society of Retina Specialists EURETINA 2019 Congress, September 5-8, 2019, Paris, France

Title:	***Suprachoroidal CLS-TA Improves Patient Outcomes in Uveitis of All Anatomic Subtypes: Results of the Phase 3 PEACHTREE Study***
Author:	Ron Neumann, M.D., Co-Chairperson ISOPT Clinical, Ocular Drug Development Expert
Summary:	Dr. Neumann presented an electronic poster for the event reviewing the results of Clearside's Phase 3, PEACHTREE study for XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), formerly known as CLS-TA. The PEACHTREE study was the first pivotal trial specifically studying macular edema due to non-infectious uveitis and the first uveitis trial with a primary endpoint of visual acuity, a significant and clinically meaningful outcome for both physicians and patients. The 96 patients treated with suprachoroidally injected CLS-TA had been diagnosed with non-infectious uveitis involving any anatomic location, reflective of clinical practice. The primary endpoint of the trial was met with nearly 1 of 2 patients experiencing a 3-line visual gain, and 1 of 2 patients experiencing resolution of macular edema. The results were consistent regardless of the anatomical location of the uveitis. There were no serious adverse events attributable to CLS-TA, and there were low rates of elevated intraocular pressure. Cataract adverse events were similar between treatment and control groups and the vast majority of CLS-TA patients did not need rescue therapy.

Conference: The Retina Society 52nd Scientific Program, September 11-15, 2019 London, UK

Title:	***Suprachoroidal Triamcinolone Acetonide Suspension (CLS-TA) and Intraocular Pressure: Results from the Phase 3 PEACHTREE Clinical Trial for Uveitis***
Author:	Pauline Merrill, M.D., Illinois Retina Associates, Rush University Medical Center
Summary:	Dr. Merrill gave an extensive presentation on the results of PEACHTREE with a focus on intraocular pressure (IOP). With respect to IOP-related adverse events (AEs), the rate was 12% in the suprachoroidal CLS-TA treatment group compared to 16% in the control group. Rescue medications were required in 72% of the patients in the control group. Ten patients in the control group experienced IOP-related AEs and each received intravitreal steroids as their rescue therapy. There were no glaucoma surgeries in either group. Further analysis found that IOP ≥ 30mmHg was observed in 5% of CLS-TA treated eyes (n=83) compared to 11% of the control eyes which received rescue treatment (n=46). Similarly, IOP lowering medications were used in fewer eyes treated with suprachoroidal triamcinolone acetonide (7%) compared to the control eyes receiving rescue treatment (13%).
Title:	***Suprachoroidal Injection of CLS-TA in Uveitis Maintains Efficacy Outcomes Through 48-weeks: Results of the MAGNOLIA Phase 3 Extension Study***

Author:	Sumit Sharma, M.D., Vitreoretinal Surgery and Uveitis Physician, Cleveland Clinic
Summary:	In the MAGNOLIA extension study, CLS-TA-treated patients maintained mean improvements of 12 letters through week 48 after their initial treatment. Half of patients did not require additional medication 36 weeks after their last injection of CLS-TA.
Title:	***Visual Acuity Outcomes and Anti-Vascular Endothelial Growth Factor Therapy Intensity in Diabetic Macular Edema: A "Real World" Analysis in 28,456 Eyes***
Author:	Thomas A Ciulla, M.D., MBA, Clearside Chief Medical Officer
Summary:	Although the introduction of anti-VEGF agents has led to notably improved outcomes for patients with diabetic macular edema (DME), there are several practical limitations, including the need for frequent injections and incomplete response in some patients. Consequently, "real world" DME treatment compliance can be poor. This analysis of 28,456 eyes showed that "real world" DME patients are under-treated and their resulting visual outcomes following anti-VEGF therapy are meaningfully less than those seen in clinical trials. This analysis demonstrates a large unmet need for DME therapies that address treatment burden and incomplete response.

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.

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