Clearside Biomedical Announces Clinical Data Presentations at The Retina Society 2020 and Publication of XIPERE™ Data in Diabetic Macular Edema in Ophthalmology Retina

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Presented the most robust aggregate dataset of suprachoroidal clinical injections demonstrating reliability and consistency of procedure

ALPHARETTA, Ga., Sept. 23, 2020 (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 several clinical data presentations were given at the virtual 53rd Annual Scientific Meeting of The Retina Society.

Clearside also announced that data from the Company's Phase 2 clinical trial in diabetic macular edema (DME) was published in *Ophthalmology Retina* and can be accessed here. The trial, entitled TYBEE, evaluated the investigational drug XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) when used with intravitreally administered aflibercept in patients with DME over a 6-month evaluation period. This early data suggests that, if approved, XIPERE administered suprachoroidally, may have the potential to reduce treatment burden for some patients.

"Our primary goal at Clearside is to deliver targeted treatments for patients suffering from serious retinal diseases," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer and Chief Development Officer. "We are committed to educating physicians and the broader retinal community on our programs. The presentations delivered this week and the publication of our work in DME underscore the broad scope of development activities for our suprachoroidal injection platform. We continue to expand our pipeline with new opportunities and indications and look forward to starting our Phase 1/2a clinical trial with CLS-AX in neovascular age-related macular degeneration (wet AMD) this year."

Title: Suprachoroidal CLS-AX (axitinib injectable suspension), as a Potential Long-Acting Therapy for Neovascular Age-Related Macular Degeneration (nAMD)
Authors: David Brown; Viral Kansara; Thomas Ciulla
Conclusions: CLS-AX was observed to be well tolerated in all animal species evaluated, with no overt signs of toxicity. There was sustained, high exposure observed in ocular tissues with the highest concentration found in the tissues of the sclera, choroid, and retinal pigment epithelium (RPE), followed by the retina. CLS-AX has intrinsic high potency, pan-VEGF inhibition through receptor blockade, and demonstrated prolonged duration observed in pharmacokinetic studies, as well as pharmacodynamic effect in multiple animal models. CLS-AX is intended to be a targeted therapy to affected tissue layers via suprachoroidal injection and has the potential to be a bi-annual therapy for wet AMD.

Title: Post Hoc Analysis of Clinical Suprachoroidal Injection Experience Across Indications
Author: Chris Henry; faculty sponsor Amy Schefler; Cherry Wan; Barry Kapik; Colette Hall; Thomas Ciulla
Conclusions: To date, this is the most robust aggregate dataset of clinical suprachoroidal injections with mounting evidence pointing to the potential reliability and consistency of the procedure. The results from the retrospective analysis demonstrated the robustness of the suprachoroidal injection regardless of indications. The two needle length options successfully accommodated for anatomical variations across patients.

Title: Suprachoroidal Delivery of Small Molecule Suspensions and Nanoparticles
Authors: Judy Kim; Viral Kansara; Thomas Ciulla
Conclusions: Delivery of small molecule suspensions may provide targeted, well-tolerated, and long-acting delivery of a wide variety of pharmacologic agents, including corticosteroids, tyrosine kinase inhibitors (TKIs), and complement inhibitors to the RPE, sclera and choroid. Preclinical models for these compounds were promising and based on the favorable clinical results of a small molecule corticosteroid for macular edema associated with noninfectious uveitis, further testing is warranted for these other molecules. Additionally, suprachoroidal delivery of DNA nanoparticle-based gene has potential as an office-based retinal gene therapy; and further testing is warranted.

Title: Suprachoroidally delivered non-viral DNA nanoparticles transfect chorioretinal cells in non-human primates and rabbits
Authors: Nancy Holekamp; Viral Kansara; Thomas Ciulla
Conclusions: Suprachoroidal injections of DNA Nanoparticles may address several unmet needs in ocular gene delivery. DNA nanoparticles are relatively non-immunogenic compared to viral vector-based gene therapy, and suprachoroidal injection facilitates the potential for office-based repeat dosing with fewer safety risks compared to subretinal injection via pars plana vitrectomy surgery. In addition, DNA nanoparticles can transfer genes beyond the capacity of viral vectors, including those in common inherited retinal diseases (IRDs) such as Stargardt disease and Usher syndrome. Additional research evaluating suprachoroidal injection in non-human primates and delivery of a therapeutic transgene is needed.

Title: Results from the Phase 3 PEACHTREE Clinical Trial: Systemic Therapy and the Efficacy of CLS-TA, a Post-Hoc Analysis
Authors: Pauline Merrill; Thomas Ciulla
Conclusions: These post hoc results corroborate the pre-specified study analyses in the PEACHTREE trial. With respect to best corrected visual acuity (BCVA) and central subfield thickness (CST), CLS-TA showed a clinically meaningful relative benefit over control in patients receiving systemic immunosuppression and patients not receiving systemic immunosuppression.

Title: Correlation of Best Corrected Visual Acuity and Central Subfield Thickness in Macular Edema Due to Retinal Vein Occlusion, Diabetic Retinopathy and Uveitis
Authors: Michael Ip; Thomas Ciulla

Conclusions: In this cohort of over 1,000 eyes, there were moderate baseline relationships between BCVA and CST in patients with macular edema (ME) due to retinal vein occlusion (RVO), diabetic macular edema (DME) and noninfectious uveitis. There were also moderate relationships between BCVA and CST across these disease states with respect to change from baseline to 6 months. These correlations provide context around the use of CST in clinical decision making.

Title: Visual Acuity Outcomes and Anti-Vascular Endothelial Growth Factor Therapy Intensity in Macular Edema Due to Retinal Vein Occlusion: An Analysis of 12,214 Eyes
Authors: Thomas Ciulla; John Pollack; David Williams
Conclusions: Real-world RVO patients with macular edema experience worse visual outcomes compared with patients in randomized controlled trials. Mean change in visual acuity (VA) correlated with treatment intensity at 1 year. Patients with better VA at presentation tended to be particularly vulnerable to vision loss.

Copies of these presentations will be available on Clearside's website under the Publications & Presentations page here: https://www.clearsidebio.com/publications.htm.

About Clearside's Suprachoroidal Space (SCS ®) Injection Platform

Clearside's patented, proprietary suprachoroidal space (SCS) injection treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. Clearside's proprietary SCS Microinjector® can be used to inject a wide variety of drug candidates that are specifically formulated to be delivered via suprachoroidal injection. The company's unique platform is inherently flexible and intended to work with established medications, new formulations of medicines, as well as future innovations such as gene therapy.

About CLS-AX (axitinib injectable suspension)

CLS-AX (axitinib injectable suspension) is a proprietary suspension of axitinib for suprachoroidal injection. Axitinib is a tyrosine kinase inhibitor (TKI) currently approved to treat renal cell cancer that achieves pan-VEGF blockade, directly inhibiting VEGF receptors-1, -2, and -3 with high potency and specificity. Clearside believes this broad VEGF blockade may have efficacy advantages over existing retinal therapies by acting at a different level of the angiogenesis cascade, and may benefit patients who sub-optimally respond to current more narrowly focused anti-VEGF therapies. Suprachoroidal injection of this proprietary suspension of axitinib has demonstrated meaningful potential in preclinical studies in multiple species. Preclinical results from Clearside and independent investigators have shown pharmacodynamic effect with reduced growth of experimental neovascularization and decreased fluorescein leakage. With suprachoroidal administration of axitinib, there is the potential to achieve prolonged duration and targeted delivery to affected tissue layers. Clearside is developing CLS-AX as a long-acting therapy for the treatment of wet AMD.

About XIPERE ™(triamcinolone acetonide suprachoroidal injectable suspension)

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 and being investigated for the treatment of macular edema associated with non-infectious 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. Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc. ("Bausch Health") (NYSE/TSX: BHC), has the exclusive license for the commercialization and development of XIPERE in the United States and Canada and exclusive options for the right to commercialize and develop XIPERE in Europe and the United Kingdom, Australia and New Zealand, and South America and Mexico (through a license agreement between Clearside and Bausch Health's affiliate). Arctic Vision, a specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE in Greater China and South Korea.

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® targets the suprachoroidal space (SCS®) and 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 development and potential benefits of CLS-AX and XIPERE, including the timing of the Phase 1/2a clinical trial for CLS-AX in wet AMD. 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, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the U.S. Securities and Exchange Commission ("SEC") on March 13, 2020, Clearside's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on August 10, 2020 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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