Clearside Biomedical Announces Multiple Presentations at the ASRS 2020 Virtual Annual Meeting

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ALPHARETTA, Ga., July 27, 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 that multiple posters and oral presentations on Clearside's pipeline and its proprietary SCS Microinjector ® targeting the suprachoroidal space (SCS®) were delivered at the American Society of Retina Specialists (ASRS) 2020 Virtual Annual Meeting.

"Clearside continues to stay top-of-mind with the ophthalmic and retina communities as our clinical development pipeline and suprachoroidal delivery system are featured at prominent medical meetings," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer and Chief Development Officer. "This year, ASRS held a successful annual meeting with a virtual format that allowed for easy access to presentations and interactions with treating physicians. We look forward to keeping our stakeholders appraised of our pipeline developments as we advance our programs."

CLS-AX (axitinib injectable suspension)

Title: Suprachoroidal CLS-AX (axitinib injectable suspension), as a Potential Long-Acting Therapy for Neovascular Age-Related Macular Degeneration (nAMD)
Authors: David Brown; Thomas Ciulla; Viral Kansara
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 demonstrated intrinsic high potency, pan-VEGF inhibition through receptor blockade, prolonged duration observed in pharmacokinetic studies, and a pharmacodynamic effect in multiple animal models. CLS-AX may be a targeted therapy for affected tissue layers via suprachoroidal injection and has the potential to be a bi-annual therapy for nAMD.

Suprachoroidal Delivery

Title: Suprachoroidal Delivery of Suspensions of Tyrosine Kinase Inhibitor, Complement Inhibitor, and Corticosteroid: Preclinical and Clinical Correlates
Authors: Steven Yeh; Thomas Ciulla, Viral Kansara
Conclusions: Suprachoroidal injection of suspensions of tyrosine kinase inhibitor (TKI), complement inhibitor, and triamcinolone acetonide demonstrated prolonged therapeutic levels with the potential for a sustained release and high bioavailability. Suprachoroidal injection showed compartmentalization with the potential to minimize adverse effects. Preclinical attributes correlated to clinical trial outcomes for steroids. Further study of TKI and complement factors suspensions are warranted.

Title: Post hoc Analysis of Clinical Suprachoroidal Injection Experience Across Retinal Disease Indications
Authors: Christopher R. Henry; Cherry Wan; Barry Kapik
Conclusions: To date, this is the largest aggregate dataset of clinical suprachoroidal injections with mounting evidence pointing to the reliability and consistency of the procedure. The two needle length options successfully accommodate for anatomical variations across patients and retinal disease states. Correlations were found between needle length, gender and injection quadrant.

Title: Post Hoc Analysis of Clinical Suprachoroidal Injection Experience for Non-infectious Uveitis
Authors: Shree Kurup; Cherry Wan, Barry Kapik
Conclusions: Overall, the two needles provided in the kit accommodated patient ocular anatomic and demographic variation. Suprachoroidal injections showed consistency across demographics and ocular characteristics. Small correlations existed between needle length used and age, injection quadrant, and disease duration. Supratemporal injection quadrant correlations were particularly consistent with previously reported anatomic variation by quadrant.

Macular Edema associated with Uveitis

Title: Variations in Intraocular Pressure Following Administration of Suprachoroidal Triamcinolone Acetonide Suspension (CLS-TA): Results from the Phase 3 PEACHTREE Clinical Trial for Uveitic Macular Edema
Authors: Quan Dong Nguyen
Conclusions: In the trial, the primary endpoint was met, with ~47% of patients gaining ≥15 Early Treatment Diabetic Retinopathy Study (ETDRS) letters. Suprachoroidally injected CLS-TA significantly improved vision and macular edema in noninfectious uveitis at all anatomical locations. There were no serious adverse events attributable to CLS-TA. Low rates of elevated intraocular pressure (IOP) and cataracts were observed, and the cataract rate was similar to the control arm.

Title: Results from the Phase 3 PEACHTREE Clinical Trial: Systemic Therapy and the Efficacy of CLS-TA, a Post-Hoc Analysis
Authors: Ashvini Reddy; Thomas A. Ciulla
Conclusions: These results corroborate the prespecified study analyses in PEACHTREE. The benefit of CLS-TA over the control in treating macular edema associated with non-infectious uveitis was noted regardless of administration of systemic therapy at baseline.

Macular Edema

Title: "Real World" Outcomes of Anti-Vascular Endothelial Growth Factor Therapy for Macular Edema Due to Retinal Vein Occlusion
Authors: Thomas A. Ciulla

Conclusions: Real-world retinal vein occlusion (RVO) patients with macular edema experience worse visual outcomes compared with patients in randomized controlled trials. Mean change in visual acuity correlates with treatment intensity at one year. Patients with better visual acuity at presentation tend to be particularly vulnerable to vision loss.

Title: Correlation of Best Corrected Visual Acuity and Central Subfield Thickness in Macular Edema Due to Retinal Vein Occlusion, Diabetic Retinopathy and Noninfectious Uveitis
Authors: Michael Ip; Thomas A Ciulla
Conclusions: There were moderate correlations between best corrected visual acuity (BCVA) and central subfield thickness (CST) in all diseases at baseline and for change at week 24. These correlations provide context around the use of CST in clinical decision making and visual recovery.

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

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 showed 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 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. 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 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 development and potential benefits of CLS-AX, CLS-TA and the SCS Microinjector. 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 filed with the SEC on May 8, 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.

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