



Clearside Biomedical Announces Multiple Medical Meeting Presentations Focused on the Advantages of Suprachoroidal Delivery and Key Differentiators in its CLS-AX Clinical Program

January 28, 2025

- *Upcoming Presentations at Angiogenesis and Macula Society Conferences to Feature CLS-AX Sub-Group Analyses from ODYSSEY Wet AMD Trial -*
- *CLS-AX Targets Flexible Dosing of Biologics with Duration of Tyrosine Kinase Inhibitors -*

ALPHARETTA, Ga., Jan. 28, 2025 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (Nasdaq: CLSD), a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS[®]), announced today recent and upcoming presentations at ophthalmic medical meetings highlighting Clearside's suprachoroidal delivery technology and promising pipeline, including its Phase 3 ready CLS-AX program for the treatment of neovascular age-related macular degeneration (wet AMD).

"Our medical meetings this quarter continue to demonstrate the commercial, clinical and regulatory expertise that establishes Clearside as the leader in suprachoroidal delivery," said Victor Chong, MD, MBA, Chief Medical Officer and EVP, Head of Research and Development. "We are excited about the potential of our CLS-AX program and look forward to presenting additional data from our Phase 2b ODYSSEY trial at upcoming meetings. We believe suprachoroidal CLS-AX has the potential to deliver comparable 6-month therapeutic effect in most wet AMD patients, similar to other intravitreal TKIs in development, while allowing physicians to have more individualized and flexible dosing options, instead of rescue, for patients who need more frequent therapy. We also believe suprachoroidal delivery enables the precise application of therapy to the retina, which may result in improved safety over other intravitreal treatment options."

Recent Sessions on Suprachoroidal Drug Delivery Utilizing Clearside's SCS Microinjector[®]:

Hawaiian Eye & Retina 2025 (January 18-24, 2025)

Presentation: *Where Are We with Suprachoroidal Delivery*
Presenter: Judy E. Kim, MD, University of Texas Southwestern Medical Center

Presentation: *Suprachoroidal Delivery of Investigational ABBV-RGX-314 for Diabetic Retinopathy: The Phase II ALTITUDE[®] Study*
Presenter: Margaret Chang, MD, MS, Retinal Consultants Medical Group

Presentation: *Tyrosine Kinases Inhibitors*
Presenter: Rishi P. Singh, MD, Cleveland Clinic

Presentation: *Suprachoroidal Delivery of Triamcinolone Injectable Suspension for Post-Operative Cystoid Macular Edema*
Presenter: Irena Tsui, MD, Doheny Eye Center UCLA

3rd Annual Ophthalmic Drug Delivery Summit (January 28-30, 2025)

Presentation: *Advancing Targeted, Compartmentalized, & Long-Acting Depot Delivery Suprachoroidal Delivery of Particulate Formulations*
Presenter: Viral Kansara, PhD, Vice President, Preclinical Development, Clearside Biomedical

Upcoming Sessions on CLS-AX Wet AMD Program

Angiogenesis, Exudation, and Degeneration 2025 (Virtual; February 8, 2025)

Presentation: *Phase 2b CLS-AX ODYSSEY Trial Results*
Presenter: Roger Goldberg, MD, MBA, Bay Area Retinal Associates Medical Group

The Macula Society 48th Annual Meeting (February 12-15, 2025)

Presentation: *Top Line Results from ODYSSEY: A Phase 2b Study of Suprachoroidally Administered CLS-AX in Participants with Neovascular Age-related Macular Degeneration*
Presenter: Thomas A. Ciulla, MD, MBA, Chief Medical Advisor-Retina and Chair, Scientific Advisory Board, Clearside Biomedical

5th Annual Wet AMD & Diabetic Eye Disease Drug Summit (March 18-20, 2025)

Presentation: *Transforming wAMD Treatment: Long-Lasting, Flexible Dosing with Suprachoroidal TKI Delivery*
Presenter: Victor Chong, MD, MBA, Chief Medical Officer, Clearside Biomedical

About Clearside's Suprachoroidal Space (SCS[®]) Injection Platform and SCS Microinjector[®]

Clearside's patent protected, 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 and new formulations of medications. Clearside's patented SCS Microinjector[®] can deliver a wide variety of drug candidates into the suprachoroidal space, providing targeted delivery to potentially improve efficacy and compartmentalization of medication to reduce or eliminate toxic effects on non-diseased cells. The SCS Microinjector is comprised of a syringe with a custom-designed hub and two 30-gauge hollow microneedles of varying lengths, each approximately one millimeter, optimizing insertion and suprachoroidal administration of drugs.

About ODYSSEY Phase 2b Clinical Trial

ODYSSEY was a randomized, double-masked, parallel-group, active-controlled, multicenter, 36-week, Phase 2b clinical trial in participants with wet AMD previously treated with intravitreal anti-vascular endothelial growth factor (VEGF) standard of care therapy. A total of 60 participants were treated for 36 weeks and randomized to either CLS-AX (1 mg) or aflibercept (2 mg) with a 2:1 randomization schedule (40 participants in CLS-AX arm and 20 participants in aflibercept arm). CLS-AX was administered via suprachoroidal injection using Clearside's SCS Microinjector, and aflibercept was administered via intravitreal injection. Participants in the trial were determined to have active disease with a median duration of wet AMD diagnosis of 9.9 months.

The ODYSSEY trial achieved its objectives, including primary outcomes in mean change from baseline in best corrected visual acuity and safety and tolerability of CLS-AX, and secondary outcomes in visual function and ocular anatomy, the need for supplemental treatment, and treatment burden as measured by total injections over the trial duration. CLS-AX demonstrated compelling intervention-free rates with 100% of CLS-AX participants not requiring any additional treatment up to 3 months, 90% up to 4 months, 81% up to 5 months, and 67% up to 6 months after the initial CLS-AX dose. In the CLS-AX group, the injection frequency was reduced by approximately 84% compared to the average monthly injections in the 24 weeks prior to screening.

About CLS-AX (axitinib injectable suspension)

Clearside is developing CLS-AX as a longer-acting therapy for the treatment of retinal diseases. CLS-AX (axitinib injectable suspension) is a proprietary suspension of axitinib for suprachoroidal injection. Axitinib is a tyrosine kinase inhibitor (TKI), currently approved as an oral tablet formulation to treat advanced renal cell carcinoma, 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 Phase 1/2a and Phase 2b wet AMD clinical trials in which CLS-AX was well tolerated and demonstrated a positive safety profile. With suprachoroidal administration of axitinib, there is the potential to achieve prolonged duration and targeted delivery to affected tissue layers by compartmentalizing axitinib behind the retina, thereby limiting drug exposure to the front of the eye.

About Clearside Biomedical, Inc.

Clearside Biomedical, Inc. is a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS[®]) to improve patient outcomes. Clearside's SCS injection platform, utilizing the Company's patented SCS Microinjector[®], enables an in-office, repeatable, non-surgical procedure for the targeted and compartmentalized delivery of a wide variety of therapies to the macula, retina, or choroid to potentially preserve and improve vision in patients with sight-threatening eye diseases. Clearside is developing its own pipeline of small molecule product candidates for administration via its SCS Microinjector. The Company's lead program, [CLS-AX \(axitinib injectable suspension\)](#), is in development for the treatment of neovascular age-related macular degeneration (wet AMD). Planning for a Phase 3 program is underway. In addition, Clearside is evaluating various small molecules for the potential long-acting treatment of geographic atrophy (GA). Clearside developed and gained approval for its first product, [XIPERE[®] \(triamcinolone acetonide injectable suspension\)](#) for suprachoroidal use, which is available in the U.S. through a commercial partner. Clearside also strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. For more information, please visit clearsidebio.com or follow us on [LinkedIn](#) and [X](#).

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 benefits of CLS-AX, Clearside's suprachoroidal delivery technology and Clearside's 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 and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission (SEC) on March 12, 2024, Clearside's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on November 12, 2024, 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.

Source: Clearside Biomedical, Inc.

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