



## **Clearside Biomedical Data Featured in Six Presentations at Association for Research in Vision and Ophthalmology (ARVO) 2025 Meeting**

May 9, 2025

### **Strong Clinical Evidence Supports Use of the Suprachoroidal Platform in Expanding the Standard of Care for the Treatment of Multiple Macular Diseases**

ALPHARETTA, Ga., May 09, 2025 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (Nasdaq: CLSD) ("Clearside" or the "Company"), a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS<sup>®</sup>), announced today that six presentations related to the Company's lead program, CLS-AX (axitinib injectable suspension), and suprachoroidal drug delivery platform were featured at the Association for Research in Vision and Ophthalmology (ARVO) 2025 Meeting.

Victor Chong, MD, MBA, Chief Medical Officer and EVP, Head of Research and Development, commented, "We are very pleased with the reception we received at ARVO this year for both our positive CLS-AX Phase 2b ODYSSEY data and our Phase 3 plans, along with our deep dive into our proficiency with suprachoroidal space (SCS<sup>®</sup>) delivery. Preclinical and clinical trial results demonstrate that CLS-AX has the potential to be a safe and long-acting therapy for wet AMD given its durability, intrinsic high potency, pan-VEGF inhibition, and proven ability to re-dose."

"It is evident that our expertise in SCS delivery, as substantiated by our advances in drug formulation and device optimization utilizing proprietary training models and segmentation algorithms for our SCS Microinjector<sup>®</sup>, establishes Clearside as the recognized leader in SCS drug delivery. These data position SCS drug delivery as a transformative approach and promising mainstream option in treating retinal diseases," concluded Dr. Chong.

In addition to the presentations, Viral Kansara, PhD, Vice President, Preclinical Development moderated an ARVO session entitled "Retina/RPE: New drugs, mechanisms of action, and toxicity" and Dr. Chong was featured on a Wet AMD/DR/RVO panel session at *Retina Unplugged*, a pre-conference of the Retina World Congress.

### **Presentation Key Highlights**

- Positive data presented from the CLS-AX Phase 2b ODYSSEY trial, which achieved the primary outcome of maintaining stable best corrected visual acuity (BCVA) with repeat dosing while meaningfully reducing the frequency of injections.
- Clearside's Phase 3 trial design to feature the flexible dosing of an anti-VEGF biologic with the duration of a pan-VEGF receptor tyrosine kinase inhibitor (TKI).
- Poster featuring data on CLS-AX, XIPERE<sup>®</sup>, and viral and non-viral gene therapy data showed that suprachoroidal drug and gene therapy delivery with Clearside's SCS Microinjector<sup>®</sup> holds a promising future for treating chorioretinal diseases.
- Clearside has developed the first ever machine learning algorithm for imaging the opening of the SCS after drug delivery for evaluating patient data.
- Clearside has developed a novel force analysis method designed to provide real-time, formulation-specific feedback that goes beyond ISO compliance, evaluate the injectability of suspensions and allow for better drug-device co-optimization. Clearside leverages these test methods to design internal drug candidate formulations and assist partners with designs specifically for suprachoroidal injection using the SCS Microinjector.
- A decade-long literature review of suprachoroidal delivery across preclinical studies and clinical trials provides key evidence to support the suprachoroidal platform as an opportunity to expand the standard of care in the treatment of macular diseases.
- The suprachoroidal injection training program with the SCS Microinjector is the only clinically validated suprachoroidal training program and over 15,000 injections have been completed to date.

### **Presentation Details**

**Title: Top Line Results from ODYSSEY: A Phase 2b Study of Suprachoroidally Administered CLS-AX in Participants with Neovascular Age-related Macular Degeneration**

Lead Author: Robert Wang, MD, Texas Retina Associates

**Title: Suprachoroidal CLS-AX (Axitinib Injectable Suspension) Offers Durability, Safety, And Therapeutic Potential for Neovascular Age-Related Macular Degeneration (nAMD) Patients: Preclinical and Clinical Corroboration**

Lead Author: Viral Kansara, PhD, Clearside Biomedical

**Title: The Evolving Role of Suprachoroidal Drug Delivery in Macular Diseases: A Decade-Long Literature Review**

Lead Author: Victor Chong, MD, MBA, Clearside Biomedical

**Title: Validation of Suprachoroidal Injection Training Program with a Synthetic Eye Model**

Lead Author: Chen-rei Wan, PhD, Clearside Biomedical

**Title: Dispensability Analysis of Suspension Formulations**

Lead Author: Darrin Rountree, MS, Clearside Biomedical

**Title: Novel Deep Learning Algorithm for Suprachoroidal Space Segmentation and Measurement in Optical Coherence Tomography**

Lead Author: Oluwagbemisola Aderibigbe, Georgia Institute of Technology

The presentations will be available on Clearside's website [here](#).

**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's Suprachoroidal Space (SCS<sup>®</sup>) Injection Platform and SCS Microinjector<sup>®</sup>**

Clearside's patent protected, proprietary suprachoroidal space (SCS<sup>®</sup>) 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<sup>®</sup> 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 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<sup>®</sup>) to improve patient outcomes. Clearside's SCS injection platform, utilizing the Company's patented SCS Microinjector<sup>®</sup>, 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<sup>®</sup> \(triamcinolone acetonide injectable suspension\)](#) 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](https://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 clinical development of Clearside's product candidates, including the Phase 3 design, the potential benefits of novel analysis methods and machine learning algorithms, and the potential benefits of CLS-AX and XIPERE<sup>®</sup>, Clearside's suprachoroidal delivery technology and Clearside's SCS Microinjector<sup>®</sup>. 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, Clearside's ability to raise additional capital, and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the U.S. Securities and Exchange Commission (SEC) on March 27, 2025, 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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Source: Clearside Biomedical, Inc.