



## **Clearside Biomedical's Lead Clinical Program CLS-AX in Wet AMD and Suprachoroidal Delivery Platform Highlighted at the 2025 Wet AMD & Diabetic Eye Disease Summit**

March 20, 2025

*- Post-Hoc Analyses Provide Comparative Data on Rescue Criteria and Intervention-Free Rates for Tyrosine Kinase Inhibitors (TKIs) in Wet AMD Development -*

*- Unique Ability to Re-Dose CLS-AX vs Rescue Supports Regulatory & Commercial Strategy -*

ALPHARETTA, Ga., March 20, 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 presentations on the Company's lead clinical program, CLS-AX (axitinib injectable suspension) in neovascular age-related macular degeneration (wet AMD), and its suprachoroidal delivery platform were delivered at the 2025 Wet AMD & Diabetic Eye Disease Summit, a scientific meeting for industry leaders, research innovators, and clinical experts dedicated to transforming the landscape of retinal vascular disease treatments.

"As the leader in suprachoroidal delivery, we valued the opportunity to participate in this industry dialogue on recent advancements and emerging therapies to improve treatment options for wet AMD and diabetic eye disease," said Victor Chong, MD, MBA, Chief Medical Officer and EVP, Head of Research and Development. "Given the high treatment burden of current anti-VEGF therapies for wet AMD, there remains a need for more sustainable and less frequent treatment while maintaining visual acuity alongside the flexibility of anti-VEGF biologics. We believe there are potential safety and efficacy benefits to using the innovative approach of delivering therapies directly to the retina, macula and choroid utilizing our SCS Microinjector<sup>®</sup>, as demonstrated in recent clinical trials of CLS-AX, the commercial product XIPERE<sup>®</sup>, and other potential therapies in development by Clearside and our licensing partners."

### **Sessions Featuring Suprachoroidal Drug Delivery for the Treatment of Wet AMD:**

#### **Transforming Wet AMD Treatment: Long-Lasting, Flexible Dosing with Suprachoroidal TKI Delivery**

Presentation by: Victor Chong, MD, MBA, Clearside Biomedical

Summary: This presentation compared the benefits of TKIs in wet AMD management, focusing on pan-VEGF receptors blockage and extended drug delivery while acknowledging the limitations of current intravitreal anti-VEGF therapies due to their modest longevity. Discussion was provided on the clinical prospects of CLS-AX for suprachoroidal injection to deliver a precise dose to retinal and choroidal tissues, without full penetration of the eye wall and low drug to-off-target tissue such as the lens. The SCS approach could potentially revolutionize treatment for wet AMD patients with additional potential safety benefits, such as no- or very-low risk of endophthalmitis and cataract. The presentation also featured new post-hoc analyses from the Phase 2b trial of CLS-AX and a detailed outline of the Phase 3 trial plans following a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA).

#### **Optimizing Clinical Trial Design & Navigating Regulatory Landscape for Wet AMD & Diabetic Eye Disease Therapies**

Presentation by: Victor Chong, MD, MBA, Clearside Biomedical

Summary: This presentation provided commentary on regulatory strategies for wet AMD development, based on recent interactions with the FDA and interpretation of the FDA's draft guidance issued in 2023. This understanding of the regulatory and treatment landscape guided Clearside's CLS-AX Phase 3 plans, which are designed to meaningfully augment clinical treatment of wet AMD, a large and growing \$12+ billion commercial market.

Dr. Chong's presentations are available on Clearside Biomedical's website in the [Publications & Presentations section](#).

#### **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 CLS-AX, CLS-AX's potential impact on the wet AMD market, as well as the potential benefits of CLS-AX, 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, 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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