Clearside Biomedical Announces Plan to Explore Strategic Alternatives to Advance its Proprietary Suprachoroidal Space (SCS®) Delivery Platform and Promising Ophthalmology Pipeline

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- Proven In-Office, Repeatable, Non-Surgical Procedure for the Targeted Delivery of a Wide Variety of Therapies for Serious Retinal Diseases -

- CLS-AX Phase 3-Ready Asset with Global Investigator Support and FDA Alignment on Pivotal Trial Program in wet AMD -

- Validated Delivery Platform with Five Commercial and Late-Stage Development Suprachoroidal Licensing Collaborations -

ALPHARETTA, Ga., July 17, 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®), today announced plans to explore a full range of strategic alternatives to advance its SCS platform and drug development pipeline to maximize stockholder value. The Company has retained Piper Sandler, a leading investment bank with substantial experience in the biotechnology industry, to support it with the strategic evaluation process. Strategic alternatives under consideration include the sale, license, monetization and/or divestiture of one or more of the Company's assets and technologies, collaboration, partnership, merger, acquisition, joint ventures, or other strategic transactions.

"We strongly believe that our proprietary suprachoroidal delivery platform provides an effective and reliable way to target challenging retinal diseases that need longer lasting treatments," said George Lasezkay, PharmD, JD, President and Chief Executive Officer. "Our SCS Microinjector ® enables a proven in-office, repeatable, non-surgical procedure for the targeted delivery of a wide variety of therapies to the macula, retina, and choroid. Based on our retinal expertise and intellectual property, we delivered the first commercial product using our SCS platform, which is now approved and commercialized in the U.S., approved in Singapore and Australia, and is currently under regulatory review in China and Canada."

Dr. Lasezkay further stated, "We have successfully produced positive and highly competitive Phase 2b clinical data for CLS-AX for the treatment of wet AMD. We are proud of the fact that the CLS-AX ODYSSEY Phase 2b trial is the only TKI clinical trial to date to achieve positive safety and efficacy results from multiple TKI dosing in wet AMD patients. Further, in February 2025, we conducted a successful end of Phase 2 meeting with the FDA through which we gained alignment on a Phase 3 development plan for CLS-AX in wet AMD. In addition, our clinical development collaboration partners continue to make progress in advancing their later-stage suprachoroidal clinical programs utilizing our SCS Microinjector in various ophthalmic disorders."

Dr. Lasezkay continued, "Clearside's innovative and pioneering achievements demonstrating the safety, simplicity and effectiveness of delivering drugs to the suprachoroidal space are the direct result of the many years of significant contributions by the current Clearside team and many of our past employees. I am proud of and grateful for their hard work and dedicated commitment to improving the lives of patients suffering from the burden of disabling, blinding diseases."

"Given the current unpredictable economic environment and challenging fundraising conditions in the biopharmaceutical industry, we are taking the necessary next steps to evaluate strategic alternatives for the Company. In order to facilitate this process and conserve cash, while continuing our support of the Company's SCS Microinjector ® licensees, all Clearside employees, including the Chief Executive Officer, Chief Financial Officer, and Chief Medical Officer, will transition into consulting roles with the Company this week. In addition, we will pause all internal research and development programs during this process," concluded Dr. Lasezkay.

No agreement providing for any strategic transaction has been reached and there can be no assurance that this process will result in any such transaction. Clearside has not set a timetable for the strategic review process. Clearside does not intend to provide updates until the Board approves a specific action or otherwise determines that disclosure is appropriate or required.

Company Highlights

SCS Injection Platform:

- The SCS Microinjector is a proven in-office, repeatable, non-surgical procedure for the targeted 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 has formulation expertise in developing small molecule suspensions that can be delivered into the suprachoroidal space, and commercial scale manufacturing capability for the SCS Microinjector that includes ISO certification.
- The Company successfully navigated the U.S. Food & Drug Administration (FDA) drug/device regulatory pathway to obtain commercial approval for its first product, XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use for the treatment of uveitic macular edema.
- A permanent CPT code is assigned in the U.S. for suprachoroidal injections permitting physicians to receive higher reimbursement for administering any drug into the SCS versus the reimbursement of the current practice of injecting drugs

into the vitreous.

Internal Pipeline - CLS-AX Program:

- CLS-AX (axitinib injectable suspension) is a proprietary suspension of axitinib for suprachoroidal injection. CLS-AX is being developed for the treatment of neovascular age-related macular degeneration (wet AMD).

- Axitinib is a tyrosine kinase inhibitor (TKI) 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.

- Age-related macular degeneration causes a progressive loss of central vision and is the most common cause of legal blindness in individuals over age 55. Wet AMD is generally caused by abnormal blood vessels that leak fluid or blood into the macula, the part of the retina responsible for central vision, and accounts for the majority of vision loss in patients with this disorder.

- Suprachoroidal injection of CLS-AX has demonstrated meaningful potential in Phase 1/2a and Phase 2b wet AMD clinical trials. These data strongly support the potential efficacy, safety and versatility of CLS-AX to treat this chronic disease.

- Clearside conducted a successful End-of-Phase 2 meeting with the FDA and aligned on the essential components of a Phase 3 program.

- The Phase 3 program is designed to maximize the commercial potential for CLS-AX with the potential to provide physicians and their patients with dosing flexibility similar to the current standard of care anti-VEGF biologics, but with the extended durability of a TKI. This combination of dosing flexibility and durability may improve outcomes and reduce the treatment burden for patients suffering from these potentially blinding retinal disorders, as well as their caregivers.

Internal Pipeline – Preclinical Small Molecule Programs:

- Clearside is evaluating various small molecules for a range of retinal diseases with high unmet medical need.

- Clearside is evaluating preclinical data on two approaches targeting Geographic Atrophy (GA) – improving choroidal perfusion and modulating pro-inflammatory cells. GA is a progressive, late-stage form of dry age-related macular degeneration characterized by well-defined areas of retinal cell loss in the macula, leading to irreversible central vision impairment. Delivery of small molecules via suprachoroidal injection enables comprehensive drug coverage of both the retina and choroid, while also potentially minimizing systemic and anterior segment side effects.

- Clearside is evaluating preclinical data on the combination of a steroid plus a TKI (axitinib formulation) for the treatment of Diabetic Macula Edema (DME). DME is the most common cause of vision loss in individuals with diabetes, in which fluid accumulates in the central part of the retina causing swelling and vision distortion due to leaky blood vessels damaged by prolonged high blood sugar.

External Licensing Agreements:

- Clearside strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic agents including gene therapies and anti-tumor agents.

- Clearside's innovative SCS Microinjector is being used in commercial ophthalmic products and promising clinical development programs by Aura Biosciences, Bausch + Lomb, BioCryst Pharmaceuticals, REGENXBIO and its global partner AbbVie, and Arctic Vision and its commercial partner Santen.

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 clinical development of CLS-AX, including the planned Phase 3 trial design, the potential benefits of CLS-AX, Clearside’s suprachoroidal delivery technology and Clearside’s SCS Microinjector ®, and Clearside’s pursuit of strategic alternatives and the entry into or completion of any strategic alternative transaction. 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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