Clearside Biomedical Extends Global Footprint with Numerous Presentations at Medical Meetings in Asia, Europe and the United States

November 25, 2024

- Commercial, Clinical and Regulatory Expertise Establish Clearside as the Leader in Suprachoroidal Delivery -

- Multiple Events at Asia-Pacific Vitreo-Retina Society Congress Highlighting Clearside's Pipeline Programs and Suprachoroidal Delivery Technology -

- Oral Presentations Delivered on ODYSSEY Wet AMD Topline Results –

ALPHARETTA, Ga., Nov. 25, 2024 (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 that presentations highlighting Clearside's suprachoroidal delivery technology and data on its pipeline programs were delivered in medical meetings in Asia, Europe and the United States.

Most prominently, Clearside's progress was featured in multiple activities at the 17 th Asia-Pacific Vitreo-Retina Society (APVRS) Congress that took place November 22-24, 2024 in Singapore. In addition, Clearside's technology and recent ODYSSEY topline data results for CLS-AX in wet AMD were highlighted at the Ophthalmology Innovation Summit (OIS) event November 22-23, 2024 in San Diego, CA and will be presented at the upcoming FLORetina 12th International Congress on OCT and OCT Angiography in Florence, Italy being held December 5-8 2024.

"We were excited to make a significant impact at the APVRS Congress in Singapore with multiple presentations and activities featuring our topline ODYSSEY results, XIPERE® real-world data, and four posters on our suprachoroidal delivery platform," said Victor Chong, M.D., MBA, Chief Medical Officer and EVP, Head of Research and Development.

Dr. Chong continued, "As our partner Arctic Vision continues to advance XIPERE towards potential approval in China, Australia, and Singapore, we have seen growing interest in our delivery approach from the medical community in the region. As a result, we hosted three separate sessions to provide demonstrations of our suprachoroidal injection procedure. These sessions enabled attendees to familiarize themselves with our SCS Microinjector® technology with hands-on testing while learning more about our novel delivery approach. We were pleased that each session reached maximum attendance capacity."

"Concurrently with APVRS, our patent protected, proprietary suprachoroidal space (SCS ®) injection treatment approach was also featured at the OIS Summit. With well over 10,000 injections performed to date with our SCS Microinjector, we were able to showcase our commercial, clinical and regulatory expertise to establish Clearside as the leader in delivery of a wide variety of therapeutic agents to the suprachoroidal space. We also look forward to extending the discussion of our progress and positive ODYSSEY results at the FLORetina Congress early next month. As we close out 2024, I am more energized than ever about our prospects heading into 2025," concluded Dr. Chong.

APVRS ACTIVITIES:

Oral Presentations:

Session: New/Upcoming Therapies for Retinal Disease
Presentation: *Topline Results from the ODYSSEY Trial*
Presenter: Victor Chong, MD, MBA, Chief Medical Officer, Clearside Biomedical

Session: General Ophthalmology Late Breaking Reports
Presentation: *Real World Use of Suprachoroidal Triamcinolone: An Iris Database Analysis*
Presenter: Michael Singer, MD, Medical Center Ophthalmology Associates, San Antonio, Texas

Poster Presentations:

Biomechanics Considerations in Suprachoroidal Drug Delivery
Presenter: Chen-rei Wan, PhD, Senior Director, Engineering, Clearside Biomedical

Targeting, Compartmentalization & Durability of Suprachoroidally Injected Small Molecule Suspensions
Presenter: Sobha Sivaprasad, DM, FRCOphth, Moorfields Eye Hospital, London

Suprachoroidal Delivery of Small Molecules and Gene Therapies for Ocular Diseases
Presenter: Sobha Sivaprasad, DM, FRCOphth, Moorfields Eye Hospital, London

Expert Guidance of Suprachoroidal Space Injection Technique
Presenter: Judy E. Kim, MD, University of Texas Southwestern Medical Center

Special Event: SCS Microinjector® Demonstration Sessions

Clearside hosted three separate suprachoroidal space (SCS®) injection procedure demonstration sessions featuring the SCS Microinjector®. These sessions featured the SCS Microinjector technology with hands-on testing and education around the novel delivery approach.

OIS & FLORetina:

Ophthalmology Innovation Summit
November 22-23, 2024 in San Diego, CA
Session: Spotlight on Suprachoroidal Drug Delivery
Presenter: Rafael Andino, Senior Vice President, Engineering & Manufacturing

FLORetina 12th International Congress on OCT and OCT Angiography
December 5-8, 2024 in Florence Italy
Symposium: Further Progress on Suprachoroidal Delivery for Ocular Therapeutics
Presentation: *Suprachoroidal Axitinib for Neovascular AMD* presented by Christopher Or, MD, Stanford University, Palo Alto, CA

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 system comprises a syringe, 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 XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use

XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use is a proprietary suspension of the corticosteroid triamcinolone acetonide for administration to the suprachoroidal space for the treatment of macular edema associated with uveitis. XIPERE is approved by the U.S. Food and Drug Administration and is commercially available in the United States. Bausch + Lomb, a leading global eye health company dedicated to helping people see better to live better, has the exclusive license for the commercialization and development of XIPERE in the U.S. and Canada. Arctic Vision, a specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE, which they refer to as Arcatus®, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. A link to the full prescribing information is available at https://www.xipere.com/hcp/#isi.

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), for the treatment of neovascular age-related macular degeneration (wet AMD), recently completed a Phase 2b clinical trial, and planning for a Phase 3 program is underway. 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 ® and the Company’s prospects for 2025. 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.

Investor and Media Contacts:

Jenny Kobin
Remy Bernarda
ir@clearsidebio.com

Source: Clearside Biomedical, Inc.