Clearside Biomedical Announces Positive Data Presentations on CLS-AX OASIS Clinical Trial and Use of SCS Microinjector® Presented at the Angiogenesis and Macula Society Annual Meetings

February 21, 2023

- CLS-AX OASIS Results Show Favorable Safety Data, Durability and Biologic Effect Over 6 Months in Treatment-Experienced Anti-VEGF Sub-Responders -

- SCS Microinjector® Featured in Favorable Data Presentations Related to Multiple Therapies in Clinical Development –

ALPHARETTA, Ga., Feb. 21, 2023 (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 several presentations were delivered at two prestigious medical conferences in February: the Angiogenesis, Exudation, and Degeneration 2023 meeting and The Macula Society 46th Annual Meeting.

"The promising durability data from our OASIS clinical trial continues to garner significant attention as a potential treatment option for patients with wet AMD," said, George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. "Our trial demonstrated that 67% of extension study participants went at least 6 months without needing additional treatment. Furthermore, detailed safety and tolerability data from OASIS reinforced the excellent safety profile for CLS-AX (axitinib injectable suspension) at all doses and timepoints for those patients with previously persistent, active disease. We were also pleased to see the promising data results from our partners utilizing our proprietary SCS Microinjector® to administer gene therapy and oncology agents to treat wet AMD, diabetic retinopathy, and choroidal melanoma."

Clearside's OASIS full clinical trial data presentation can be accessed on the Company's Events and Presentations page.

Clearside's medical meeting presentations can be accessed on the Company's Publications and Presentations page.

Angiogenesis, Exudation, and Degeneration 2023 – Virtual Edition

Presentation Title: Suprachoroidal Therapy for Neovascular AMD

Presented by: Mark R. Barakat, M.D., Director of Retinal Research Institute, Retinal Consultants of Arizona, and Clinical Assistant Professor of Ophthalmology, University of Arizona College of Medicine - Phoenix

Dr. Barakat presented data on two key programs in neovascular age-related macular degeneration (wet AMD) utilizing Clearside's SCS Microinjector for suprachoroidal delivery.

The results from Clearside's OASIS Phase 1/2a clinical trial were featured. In the trial, CLS-AX was well tolerated and demonstrated an excellent safety profile across all timepoints and doses. CLS-AX showed promising durability and biologic effect over six months in difficult-to-treat patients who were heavily treatment experienced anti-VEGF sub-responders. The data showed that 67% of participants in the extension study went at least 6 months without needing additional treatment, and 50% of participants went beyond six months. Overall, extension study participants experienced a 77% - 85% reduction in treatment burden. Plans for Clearside's Phase 2b ODYSSEY clinical trial were also described in the presentation.

Dr. Barakat also presented data from Clearside's partner, REGENXBIO, from its Phase 2 AAVIATE clinical trial utilizing RGX-314, a gene therapy delivered via suprachoroidal injection to treat wet AMD. The presentation summarized results showing that suprachoroidal RGX-314 has been well tolerated in cohorts 1-5 (n=85).

Presentation Title: Suprachoroidal Therapy for Diabetic Retinopathy
Presented by Dr. Peter Campochiaro on behalf of REGENXBIO

The Macula Society 46th Annual Meeting

Presentation Title: Safety and Tolerability Study of Suprachoroidal Injection of CLS-AX in Neovascular AMD Patients with Persistent Activity Following Anti-VEGF Therapy (OASIS)

Presented by: Baruch D. Kuppermann, M.D., Ph.D., Roger F. Steinert Professor, Chair of the Department of Ophthalmology, and Director of the Gavin Herbert Eye Institute at the University of California, Irvine. He also holds a joint appointment with the Department of Biomedical Engineering at UC Irvine

Dr. Kuppermann presented a summary of the 6-Month Extension Study results from Clearside's CLS-AX OASIS Phase 1/2a clinical trial in participants with wet AMD. The presentation featured the rationale for utilizing CLS-AX in this indication as the agent utilizes Clearside's proprietary suspension formulation combined with the high potency and pan-VEGF inhibition of the TKI axitinib delivered via Clearside's SCS Microinjector. This targeted delivery approach to affected tissues may improve the treatment landscape with potential safety, efficacy, durability, and adoption benefits. The Extension Study results showed that CLS-AX had an excellent safety profile and had promising durability with a meaningful reduction in treatment burden across cohorts of between 77% - 85%. The study also showed stable central subfield thickness and stable best corrected visual acuity throughout the treatment period.

Presentation Title: A Phase 2 Trial of Belzupacap Sarotalocan (AU-011): An Investigational Targeted Therapy for Choroidal Melanoma via

Suprachoroidal Administration

Presented by Dr. Ivana Kim on behalf of the Belzupacap Sarotalocan Investigator Group

Clearside's partner Aura Biosciences announced Dr. Kim's presentation of positive interim Phase 2 safety and efficacy data of belzupacap sarotalocan (bel-sar) with 9-10 months of follow up evaluating two key clinical endpoints: tumor control and visual acuity preservation using the suprachoroidal route of administration for the first-line treatment of patients with early-stage choroidal melanoma. The data presented showed an excellent response to the therapy with 89-100% tumor control, and a favorable safety profile to date.

Presentation Title: Suprachoroidal Delivery of RGX-314 for Diabetic Retinopathy: The Phase II ALTITUDE® Study
Presented by Dr. Dennis Marcus on behalf of REGENXBIO

About CLS-AX (axitinib injectable suspension)

CLS-AX (axitinib injectable suspension) is a proprietary suspension of axitinib for suprachoroidal injection. Axitinib is a tyrosine kinase inhibitor (TKI) currently approved to treat renal cell cancer 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 preclinical studies in multiple species and in a Phase 1/2a clinical trial. With suprachoroidal administration of axitinib, there is the potential to achieve prolonged duration and targeted delivery to affected tissue layers. Clearside is developing CLS-AX as a long-acting therapy for the treatment of retinal diseases.

About the OASIS Phase 1/2a Clinical Trial

OASIS was an open-label, dose-escalation Phase 1/2a trial in wet AMD participants to assess the safety and tolerability of a single dose of CLS-AX administered by suprachoroidal injection via Clearside's SCS Microinjector ®. Eligible participants were those who demonstrated stable visual acuity following two or more previous injections with an intravitreal anti-VEGF agent. All enrolled participants underwent diagnostic imaging on screening, followed by masked reading center confirmation of persistent active disease.

The study included four cohorts totaling 27 patients at the following doses: Cohort 1 at 0.03 mg; Cohort 2 at 0.1 mg; Cohort 3 at 0.5 mg; Cohort 4 at 1.0 mg. Enrolled patients received aflibercept at the first visit followed by a single dose of CLS-AX at the second visit one month later. The primary endpoint for the trial was assessment of the safety and tolerability of CLS-AX for the 3 months following the administration of CLS-AX, and secondary endpoints evaluated the pharmacokinetics, visual function, ocular anatomy, and the need for additional treatment with intravitreal aflibercept.

A 3-month Extension Study was conducted to follow patients in Cohorts 2, 3 and 4 who chose to continue for a total of six months. Additional information on the Phase 1/2a trial can be found on clinicaltrials.gov NCT04626128 and the extension study can be found at NCT05131646.

About Clearside's SCS Microinjector ®

Clearside's patented, proprietary suprachoroidal space (SCS ®) injection treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. Clearside's proprietary SCS Microinjector can be used to inject a wide variety of drug candidates into the SCS. The SCS Microinjector provides targeted delivery to potentially improve efficacy and compartmentalization of medication to reduce or eliminate toxic effects on non-diseased cells. The SCS Microinjector is composed of a syringe and two 30-gauge hollow microneedles of varying lengths, each less than 1.2 millimeters, within a custom-designed hub that optimizes insertion and suprachoroidal administration of drugs.

About Neovascular Age-Related Macular Degeneration (wet AMD)

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. In the U.S., approximately 11 million patients are living with AMD, and about 20% have the wet form. Current treatments require life-long, frequent injections to maintain efficacy. This treatment regimen tends to cause a treatment burden for patients resulting in reduced compliance and under-treatment leading to potentially limited outcomes.

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®). Clearside's SCS injection platform, utilizing the Company's proprietary 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 and strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. Clearside's first product, XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, is commercially available in the U.S. For more information, please visit www.clearsidebio.com.

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, including the timing of safety data from the OASIS clinical trial, and the potential benefits, of CLS-AX and therapies using 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, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission (SEC) on March 11, 2022, 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
(678) 430-8206

Source: Clearside Biomedical, Inc.