Clearside Biomedical Highlights Excellent Safety Profile of CLS-AX and Potential for Extended Duration of Effect in Data Presentation at the American Society of Retina Specialists 41st Annual Scientific Meeting

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- Suprachoroidal Injection of CLS-AX Resulted in Favorable Safety Data, Durability and Biologic Effect Over 6 Months -

ALPHARETTA, Ga., July 31, 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 safety and tolerability data from its recent OASIS clinical trial of CLS-AX (axitinib injectable suspension) were presented at the American Society of Retina Specialists (ASRS) 41st Annual Scientific Meeting. CLS-AX is a proprietary suspension formulation of the tyrosine kinase inhibitor (TKI) axitinib that provides high potency pan-VEGF inhibition delivered via Clearside's proprietary SCS Microinjector ®.

The presentation, entitled, "Safety and Tolerability of Suprachoroidal Injection of CLS-AX in Neovascular AMD Patients With Persistent Activity After Anti-VEGF Therapy" was delivered by Rahul N. Khurana, MD, FACRS, Northern California Retina Vitreous Associates. Dr. Khurana presented data from Clearside's OASIS Phase 1/2a clinical trial and Extension Study highlighting the excellent safety profile with no serious adverse events (SAEs), no adverse events (AEs) from inflammation, no vasculitis or vascular occlusion, and no treatment emergent adverse events (TEAEs) related to study treatment.

"The safety profile for new potential treatments in development for wet AMD and other retinal diseases is of paramount importance to physicians and patients. CLS-AX has demonstrated an excellent safety profile to date with no adverse events, and in particular, no inflammation," said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. "Our treatment approach utilizing our SCS Microinjector is a reliable, in-office, non-surgical, non-implant delivery mechanism to deliver the most potent TKI in development for patients with wet AMD. In addition, we believe that the stable vision and extended duration of effect we observed in OASIS and the Extension Study will carry forward to our ODYSSEY Phase 2b clinical trial currently enrolling participants in the U.S."

The presentation described the promising results from the 6-Month Extension Study at higher doses in Cohort 3 and Cohort 4. These cohorts showed signs of durability and a 77% - 85% reduction in treatment burden. Additionally, signs of biologic effect with stable mean best corrected visual acuity (BCVA) and stable mean central subfield thickness (CST) to the 6-month timepoint were seen in these cohorts.

OASIS was an open-label, single dose-escalation Phase 1/2a trial in neovascular age-related macular degeneration (wet AMD). OASIS was a 3-month trial, followed by a 3-month Extension Study. The trial included four cohorts 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. Participants from Cohorts 2, 3 and 4 who rolled over into the Extension Study were followed for a total of 6 months after a single dose of CLS-AX. Participants enrolled in OASIS were heavily anti-VEGF treatment experienced with active disease at screening, which was confirmed by an independent reading center.

Clearside's suprachoroidal delivery platform is also featured at ASRS in presentations related to several partner programs:

- Suprachoroidal Delivery of RGX-314 for Neovascular AMD: Results of the Phase II AAVIATE Study
- Suprachoroidal Delivery of RGX-314 Gene Therapy for Diabetic Retinopathy: The Phase II ALTITUDE Study
- Phase 2 Trial of Belzupacap Sarotalocan (Bel-Sar, AU-011), a Targeted Therapy for Choroidal Melanoma via Suprachoroidal Administration

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 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 preclinical studies in multiple species and in a Phase 1/2a wet AMD clinical trial in which CLS-AX was well tolerated and demonstrated an excellent safety profile. With suprachoroidal administration of axitinib, there is the potential to achieve prolonged duration and targeted delivery to affected tissue layers while limiting drug exposure to the front of the eye. Clearside is developing CLS-AX as a long-acting therapy for the treatment of retinal diseases.

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 less than 1.2 millimeters, 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®). 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), is in Phase 2b clinical testing. 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.

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, 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 and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the U.S. Securities and Exchange Commission (SEC) on March 14, 2023 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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