Clearside Biomedical's Versatile Suprachoroidal Injection Platform Highlighted in Four Ophthalmic Indications in Clinical Data Presentations at AAO 2023 Annual Meeting

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Robust Safety Profile and Encouraging Efficacy Data Utilizing SCS Microinjector® Featured in Multiple Data Presentations

ALPHARETTA, Ga., Nov. 07, 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 multiple oral and poster presentations were delivered at the Annual Meeting of the American Academy of Ophthalmology (AAO) that highlighted encouraging safety and efficacy data from clinical trials of therapies utilizing Clearside's SCS Microinjector ® to deliver drug candidates into the suprachoroidal space to treat a variety of retinal diseases.

"The AAO meeting held over the past week was exceptionally positive for Clearside and our clinical development partners," said, George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. "The presentation of OASIS data demonstrates the potential for CLS-AX to be a long-term maintenance therapy for wet AMD by maintaining visual acuity and reducing treatment burden. Two of our partners, REGENXBIO and Aura Biosciences, presented new, positive Phase 2 safety and clinical efficacy data from their respective programs utilizing our SCS Microinjector. Aura also announced that they have received a Special Protocol Assessment from the FDA for the design of their Phase 3 clinical trial in choroidal melanoma that will utilize our SCS Microinjector."

"The data at AAO utilizing our SCS Microinjector evaluated both small molecules and gene therapy spanning four indications: wet AMD, uveitic macular edema, diabetic retinopathy and choroidal melanoma. Taken together, it is clear that we are the leader and the partner of choice in delivering agents into the suprachoroidal space to improve outcomes for patients suffering from a variety of retinal disease," concluded Dr. Lasezkay.

Title: Safety and Tolerability of Suprachoroidal CLS-AX (Axitinib Injectable Suspension) in nAMD Patients in a Phase 1/2a Study, OASIS
Presented by: Rahul N. Khurana, M.D.
Summary: This presentation summarized the promising data from Clearside's 3-month OASIS clinical trial and Extension Study through 6 months. OASIS was an open-label, single 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. CLS-AX is a proprietary suspension formulation of the tyrosine kinase inhibitor (TKI) axitinib that provides high potency pan-VEGF inhibition. In the study, CLS-AX demonstrated an excellent safety profile at all doses and timepoints, with no serious adverse events, no dose limiting toxicities, and no adverse events from inflammation. CLS-AX also exhibited early signs of durability and reduction in treatment burden. CLS-AX is currently being evaluated in a Phase 2b clinical trial, ODYSSEY, for wet AMD.

Partner: REGENXBIO
Title: ALTITUDE: Suprachoroidal Delivery of ABBV-RGX-314 Investigational Gene Therapy for Diabetic Retinopathy
Presented by: Mark R. Barakat M.D. as a Late Breaker Development
Summary: ALTITUDE is a multi-center, open-label, randomized, controlled, dose-escalation trial evaluating the efficacy, safety and tolerability of suprachoroidal delivery of ABBV-RGX-314 using the SCS Microinjector in patients with diabetic retinopathy. The presentation of data showed that ABBV-RGX-314 was well tolerated in 50 patients from dose levels 1 and 2 (Cohorts 1-3) with no drug-related serious adverse events. Dose level 2 prevented disease progression and reduced vision-threatening events in non-proliferative diabetic retinopathy patients at 1 Year. To date, 70.8% of patients achieved Diabetic Retinopathy Severity Scale improvement vs. 25.0% in control, 0% of patients worsened ≥ 2 steps vs. 37.5% in control and ABBV-RGX-314 reduced vision-threatening events by 89%.

Partner: AURA Biosciences
Title: A Phase 2 Trial of Belzupacap Sarotalocan, a Targeted Investigational Therapy for Choroidal Melanoma via Suprachoroidal Administration
Presented by: Carol L. Shields, M.D.
Summary: The presentation described data from Aura's Phase 2 trial assessing the safety and preliminary efficacy of single- and multiple ascending-doses of bel-sar delivered by suprachoroidal administration with Clearside's SCS Microinjector for the first-line treatment of early-stage choroidal melanoma. The results, with 90% of patients at twelve months of follow-up who received three cycles of therapy in Cohorts 5 and 6, and who match the criteria for the global Phase 3 trial, showed a tumor control rate of 80% (8/10) and the visual acuity preservation rate was 90% (9/10). The majority of patients were at high-risk for vision loss with tumors close to the fovea or optic disk. For the 80% of patients that responded, data showed a statistically significant reduction in tumor growth rate (-0.382 mm/yr, p = <0.0001) compared to each patient's documented growth rate at study entry. The overall tolerability profile of bel-sar was favorable, with no dose-limiting toxicities, treatment-related SAEs or significant AEs reported as of August 3, 2023.

Partner: Bausch + Lomb
Title: Experience With Triamcinolone Acetonide Suprachoroidal Injection for Uveitic Macular Edema: A Physician Survey
Presented by: Michael A. Singer, M.D.
Summary: The poster reported results of a survey on physicians' early experience with suprachoroidal injection of XIPERE for uveitic macular edema. No new safety signals emerged. The findings from the survey indicated that physicians found the XIPERE injection easy to learn, with patient outcomes consistent with clinical trial data.

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

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 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 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 utilizes its patented SCS Microinjector ®, the first and only FDA-approved way to access the suprachoroidal space. Clearside's 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 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 is developing its own pipeline of small molecule product candidates for administration via its SCS Microinjector. Clearside's lead suprachoroidal development program, CLS-AX (axitinib injectable suspension), is in Phase 2b clinical testing for the treatment of neovascular age-related macular degeneration (wet AMD). Clearside also strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. For more information, please visit clearsidebio.com and follow us on LinkedIn and TwitterX.

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 timing of clinical trials as well as the potential benefits of Clearside's product candidates, suprachoroidal delivery technology and 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, Clearside's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 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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