Positive Data Presentations at AAO Annual Meeting Demonstrate Utility and Versatility of Clearside Biomedical's Proprietary Suprachoroidal Space Platform

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- Favorable Safety Profiles and Encouraging Efficacy Data Reported in Clinical Trials in the Suprachoroidal Space (SCS®) Across Multiple Therapeutic Areas using Clearside's SCS Microinjector ® -

- SCS Microinjector® Featured in Multiple Oral and Poster Presentations at Recent American Academy of Ophthalmology (AAO) 2022 Annual Meeting -

ALPHARETTA, Ga., Oct. 04, 2022 (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 clinical data from multiple internal and partnered programs were presented at the recent 2022 Annual Meeting of the American Academy of Ophthalmology (AAO), the world's largest association of eye physicians and surgeons.

"These data presentations are very exciting, demonstrating the flexibility of suprachoroidal delivery via our SCS Microinjector across a number of different ophthalmic indications," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer and Chief Development Officer. "This clinical data validates the significant potential of our patented platform to deliver therapeutics as varied as gene therapy, virus-like drug conjugates, and small molecules directly to the back of the eye in an office-based, non-surgical procedure. The interest of the medical community in delivering drugs to the suprachoroidal space is extraordinary."

"Clearside is the established leader in the SCS space. With our internal CLS-AX small molecule program and several partnered programs, there are currently four therapies in development and six clinical trials underway globally using our SCS Microinjector delivery platform. We look forward to additional near-term data being generated and reported across all of these clinical-stage programs," Dr. Ciulla concluded.

Aura Biosciences Inc. (NASDAQ: AURA) Interim Safety and Efficacy Data from the Ongoing Phase 2 Trial of AU-011 Using Suprachoroidal Administration

- This Phase 2 trial (NCT04417530) is assessing the safety and preliminary efficacy of single- and multiple ascending-doses of belzupacap sarotalocan (AU-011) up to three cycles of treatment via SCS administration for the first-line treatment of early-stage choroidal melanoma (IL/CM).
- A total of 20 adult patients have been enrolled in the trial including the single dose Cohorts 1-3 (n=6) and multiple dose escalation Cohorts 4-6 (n=14). Cohorts 5 and 6 received up to three cycles of therapy, which was considered the therapeutic regimen for evaluation. One patient in Cohort 5 (n=3) received two cycles of therapy and two patients in Cohort 5 received three cycles of therapy (40 µg/dose). All patients from Cohort 6 (n=8) received three cycles of therapy at the highest dose (80 µg/dose). One patient from Cohort 6, who discontinued after one cycle due to unrelated serious adverse events (SAEs), is not included.
- All patients in Cohorts 5 and 6 had active growth at study entry, as an enrichment strategy to evaluate preliminary efficacy. This group of patients with active growth treated at the therapeutic regimen of three cycles was evaluated for tumor growth rate, tumor control, and visual acuity preservation as the defined clinical endpoints to evaluate preliminary efficacy. These endpoints have been discussed with the U.S. Food and Drug Administration and are planned to be used in the pivotal program.
- The results, with an average of six months follow up in patients that received three cycles of therapy in Cohorts 5 and 6, showed a statistically significant reduction in the tumor growth rate (-0.296 mm/yr, p = 0.0007) compared to each patient's documented growth rate at study entry, and an 88.9% (8/9) tumor control rate. In addition, the visual acuity preservation rate was 88.9% (8/9) in these cohorts, with the majority of patients being at high-risk for vision loss with tumors close to fovea or optic disk.
- The overall safety profile of belzupacap sarotalocan was generally favorable, with no dose-limiting toxicities or treatment-related SAEs reported as of August 19, 2022. There was no posterior inflammation and only mild anterior inflammation (Grade 1) in 20% of the patients. Treatment-related adverse events (AEs) were predominantly mild and resolved without sequalae.

REGENXBIO Inc. (Nasdaq: RGNX) Data Summary and Safety Update for the Phase 2 AAVIATE Trial of RGX-314 using Suprachoroidal Delivery

- The Phase 2 AAVIATE trial of RGX-314 for the treatment of wet AMD using in-office suprachoroidal delivery continues to show positive interim results. AAVIATE is a multi-center, open-label, randomized, active-controlled, dose-escalation trial that is evaluating the efficacy, safety and tolerability of suprachoroidal delivery of RGX-314. The primary endpoint of the

trial is mean change in vision in patients dosed with RGX-314, as measured by best corrected visual acuity (BCVA) at Week 40 from baseline, compared to patients receiving monthly injections of ranibizumab. Other endpoints include mean change in central retinal thickness (CRT) and number of anti-vascular endothelial growth factor (anti-VEGF) intravitreal injections received following administration of RGX-314.

- As of August 1, 2022, RGX-314 suprachoroidal delivery was reported to be well tolerated across 85 patients dosed in Cohorts 1-5. Fifteen SAEs were reported, none of which were considered related to RGX-314. For the total group of Cohorts 1-4 (n=65), all common treatment emergent adverse events through 6 months in the study eye were mild or moderate and included conjunctival hemorrhage, increased intraocular pressure, episcleritis, and conjunctival hyperemia. Mild intraocular inflammation was reported at similar incidence in the first and second dose levels, with an increase in incidence in mild to moderate inflammation seen at the third dose level (Cohort 4). All intraocular inflammation resolved with topical corticosteroids.
- Patients treated in the RGX-314 arms and the ranibizumab control arm both continue to demonstrate stable BCVA and CRT at 6 months. In addition, a meaningful reduction in anti-VEGF treatment burden following administration of RGX-314 compared to mean annualized injection rate during the 12 months prior to administration was observed and ranged from -63.8% to -84.7% across all cohorts. The highest reduction in treatment burden was observed in the third dose level, with patients receiving a mean of 1.3 injections over six months following administration of RGX-314, which represents an 84.7% reduction in anti-VEGF treatment burden. Ten out of 15 patients (67%) in the third dose level received no anti-VEGF injections over six months following RGX-314 administration. In these patients, visual acuity and CRT was observed to be stable over six months.
- Additionally, the interim data from the second dose level (Cohorts 2 and 3) suggests there is no meaningful difference in safety and vision outcomes for patients who are neutralizing antibody (NAb) positive.

Bausch + Lomb Corporation (NYSE/TSX: BLCO) Related Presentations on XIPERE® (triamcinolone acetonide injectable suspension) for Suprachoroidal Use

- Suprachoroidal Triamcinolone Acetonide for Macular Edema Associated with Uveitis: Outcomes by Various Uveitis Subtypes in PEACHTREE. Shah et al.
- Suprachoroidal Use of Triamcinolone Acetonide: A Post-Hoc Analysis of PEACHTREE to Evaluate Elevations in Intraocular Pressure. Or et al.
- Efficacy of Suprachoroidal Triamcinolone Acetonide in the Treatment of Uveitic Macular Edema in Patients with Earlier vs. Later Disease. Uchiyama et al.

Clearside Biomedical Presentation on CLS-AX (axitinib injectable suspension) at Eyecelerator @ AAO 2022 Retina Showcase

- Presentation highlighted the potential benefits of combining pan-VEGF inhibition from the highly potent tyrosine kinase inhibitor, axitinib, with targeted delivery to affected chorioretinal tissues utilizing Clearside's proprietary SCS Microinjector ®.

About Clearside Biomedical

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.

Investor and Media Contacts: Jenny Kobin Remy Bernarda ir@clearsidebio.com (678) 430-8206