Clearside Biomedical's Leadership in Suprachoroidal Delivery Featured in Multiple Presentations at the Clinical Trials at the Summit Meeting

June 12, 2024

- Broad Use of Suprachoroidal Injection Platform Highlighted Across Retinal Indications -

- Robust Safety Profile and Encouraging Efficacy Data Reported Utilizing SCS Microinjector® -

ALPHARETTA, Ga., June 12, 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 multiple oral presentations were delivered at the Clinical Trials at the Summit (CTS) Meeting on June 8, 2024 in Park City, Utah. These presentations highlighted the versatility and potential advantages of suprachoroidal administration of therapeutics in treating retinal diseases.

"Clearside is leading the way in suprachoroidal delivery, including having the only FDA approved product for suprachoroidal use and a second program with an expected near-term clinical data readout for CLS-AX in the large wet AMD market," said Victor Chong, M.D., MBA, Chief Medical Officer of Clearside. "We believe that suprachoroidal delivery combined with the differentiated mechanism of action and high potency of axitinib offers the potential for CLS-AX to be a long-term maintenance therapy for wet AMD patients. In addition, our licensing partners continue to report encouraging clinical data from their development programs. Collectively, there are four potential therapies in clinical development with suprachoroidal delivery targeting five different serious opthalmic indications."

Title: Suprachoroidal Drug Delivery in the Real World
Presented by: Glenn Yiu , M.D., PhD
Summary:

- Suprachoroidal injections are a new and innovative technique that may provide improved bioavailability to the posterior segment of the eye while minimizing exposure and adverse effects on the anterior segment.
- Real-world data on the use of XIPERE® (triamcinolone acetonide injectable suspension), for the treatment of macular edema associated with uveitis, showed excellent durability in which more than 75% of eyes did not require retreatment for 6 months after a single dose of XIPERE.
- Suprachoroidal injections can be easily performed in an office-based setting with special considerations that are different from conventional intravitreal injections including needle selection and optimal delivery technique.
- Potential applications beyond delivering steroids, such as angiogenesis inhibitors and gene therapies, may broaden the scope of suprachoroidal delivery in ophthalmic practice.

Title: Update on CLS-AX for nAMD
Presented by: Lejla Vajzovic, M.D., FASRS
Summary:

- Clearside is utilizing its patented suprachoroidal injection technology to deliver CLS-AX, a small molecule suspension of the tyrosine kinase inhibitor, axitinib, for the treatment of neovascular age-related macular degeneration (wet AMD).
- With thousands of suprachoroidal injections performed to date, the safety profile of the SCS Microinjector® is comparable to intravitreal injections.
- OASIS, the dose ranging Phase 1/2a study of CLS-AX in wet AMD, demonstrated an excellent safety profile, promising durability and biologic effect.
- ODYSSEY, the 36-week randomized, double-masked Phase 2b clinical trial of CLS-AX in 60 participants with wet AMD, is ongoing with topline data expected in Q3 2024. The ODYSSEY trial is differentiated from other mid-phase wet AMD studies, as it required enrollment of patients with confirmed, active disease and allows re-treatment with CLS-AX to provide multi-dosing data in a chronic disease.

Additional Presentations Delivered by Clearside Commercial and Development Partners

Partner: REGENXBIO
Title: Suprachoroidal Delivery of Investigational ABBV-RGX-314 Gene Therapy for DR: The Phase 2 ALTITUDE Study
Presented by: Raj Maturi, M.D.

Partner: Aura Biosciences
Title: A New Potential Option for Uveal Melanoma - The Science of Bel-Sar and Phase 3 CoMpass Trial
Presented by: Ross Goldstein, M.D., MBA

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 by compartmentalizing axitinib behind the retina and thereby 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, 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 and 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 clinical development of CLS-AX and the expected timing of topline results from the ODYSSEY clinical trial as well as the potential benefits of CLS-AX, Clearside's suprachoroidal delivery technology and 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, 2023, filed with the U.S. Securities and Exchange Commission (SEC) on March 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.

Source: Clearside Biomedical, Inc.

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