Clearside Biomedical Announces Completion of Final Participant Visit in ODYSSEY Phase 2b Trial of CLS-AX in Wet AMD

August 27, 2024

- CLS-AX is a Highly Potent Tyrosine Kinase Inhibitor Delivered Suprachoroidally Using Clearside's Proprietary SCS Microinjector ® -

- Topline Data Expected to be Reported During the Week of October 7, 2024 -

ALPHARETTA, Ga., Aug. 27, 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 the completion of the final participant visit in the Company's ODYSSEY Phase 2b clinical trial of CLS-AX (axitinib injectable suspension) in neovascular age-related macular degeneration (wet AMD). With this milestone complete, the study database is being cleaned and verified. Then the database will be locked and the unblinded data will be analyzed, with topline results expected to be reported during the week of October 7, 2024.

"The completion of our ODYSSEY trial represents a major accomplishment for Clearside and I would like to recognize the Clearside team for the hard work and dedication in conducting the trial and achieving this important milestone," said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. "We would also like to extend our sincere appreciation to the participants, clinical sites, and the physician investigators involved in ODYSSEY. At Clearside, we believe there is a compelling market opportunity for CLS-AX to provide patients and physicians with a potentially safer treatment option and reduced treatment burden using axitinib, the highly-potent tyrosine kinase inhibitor (TKI), combined with delivery into the suprachoroidal space using our patented SCS Microinjector®. We look forward to reporting the topline data and also presenting the data at events ahead of the annual meeting of the American Academy of Ophthalmology (AAO) in Chicago."

About the ODYSSEY Phase 2b Clinical Trial

ODYSSEY is a randomized, double-masked, parallel-group, active-controlled, multi-center, 36-week Phase 2b clinical trial in participants with wet AMD. A total of 60 participants were expected to be treated for 36 weeks and randomized to either CLS-AX (1 mg) or aflibercept (2 mg) with a 2:1 randomization schedule (40 participants in CLS-AX arm and 20 participants in aflibercept arm). CLS-AX was administered by suprachoroidal injection via Clearside's SCS Microinjector, and aflibercept was administered via intravitreal injection. Eligible participants were treatment-experienced and underwent diagnostic imaging at their screening visit followed by masked reading center confirmation of persistent active disease. The primary outcome measure is the mean change from baseline in best corrected visual acuity. Secondary outcome measures include other changes from baseline in visual function and ocular anatomy, the need for supplemental treatment, and treatment burden as measured by total injections over the trial duration. The trial is designed to provide the necessary parameters to design a Phase 3 program. Additional information about the Phase 2b trial can be found on clinicaltrials.gov (NCT05891548).

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, thereby limiting drug exposure to the front of the eye. Clearside is developing CLS-AX as a longer-acting therapy for the treatment of retinal diseases.

About Age-Related Macular Degeneration (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. Neovascular AMD (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[1], and about 10% have the wet form[2]. 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. In the U.S., the total economic impact of late-stage AMD is estimated to be approximately $49 billion, with the majority of costs attributed to lower productivity related to job loss or job reduction due to the condition[3].

Sources

[1] Pennington, Katie L and DeAngelis, Margaret M, Eye and Vision, Epidemiology of age-related macular degeneration (AMD): associations with cardiovascular disease phenotypes and lipid factors, Dec 22, 2016.

[2] Prall, F Ryan and Ciulla, Thomas A, Medscape: Exudative (Wet) Age-Related Macular Degeneration (AMD), June 16, 2022.

[3] Retina International, The Socio-economic Impact of Age-related Macular Degeneration (AMD) in Bulgaria, Germany, and USA, Oct 12, 2022.

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.

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, the expected timing of topline results from the ODYSSEY clinical trial and 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, Clearside's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 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.

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