



Clearside Biomedical Completes Recruitment in ODYSSEY Phase 2b Clinical Trial of CLS-AX in Wet AMD

November 1, 2023

- Successful Completion of Recruitment Driven by Strong Clinical Site Participation and Investigator Support -

- Topline Data Expected in Q3 2024 -

ALPHARETTA, Ga., Nov. 01, 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 the completion of recruitment in its ODYSSEY Phase 2b clinical trial, a randomized, double-masked, parallel-group, active-controlled, multi-center study in participants with neovascular age-related macular degeneration (wet AMD). ODYSSEY is evaluating the safety and efficacy of CLS-AX (axitinib injectable suspension), a highly potent tyrosine kinase inhibitor delivered directly to the site of disease via Clearside's SCS Microinjector[®].

Following the completion of recruitment, final participants will be randomized to the CLS-AX treatment arm or the aflibercept comparator arm by the middle of December 2023. The Company expects to report topline data in the third quarter of 2024.

"The completion of recruitment in ODYSSEY is a critical achievement for Clearside as we strive to bring an improved therapy to the millions of individuals living with wet AMD, a common cause of legal blindness in individuals over age 55," said, George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. "The efficacy and safety results from the study will guide the path forward for our pivotal Phase 3 development program for CLS-AX. We would like to thank the clinical trial participants, investigators, and sites whose significant interest in CLS-AX drove strong recruitment for the study as we pursue the common goal of improving treatment for wet AMD."

"In ODYSSEY, we are looking to replicate the excellent safety profile, stable vision, and reduced frequency of injections we observed in our OASIS Phase 1/2a trial and its 3-month Extension Study. The differentiated mechanism of action and high potency of axitinib combined with safe and reliable delivery into the suprachoroidal space with our proprietary SCS Microinjector has the potential to be a best-in-class approach for long-term maintenance therapy for wet AMD patients," concluded Dr. Lasezkay.

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. The study is designed to evaluate at least 60 participants 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 is administered by suprachoroidal injection via Clearside's SCS Microinjector, and aflibercept is 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 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 \(NCT05891548\)](https://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 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 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 AMD¹, and about 10% have the wet form². 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 condition³.

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 and other product candidates 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, Clearside's Quarterly Report on Form 10-K 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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