Clearside Biomedical Opens Enrollment in ODYSSEY Phase 2b Clinical Trial of CLS-AX (axitinib injectable suspension) in Wet AMD

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- U.S. Clinical Sites Screening Treatment-Experienced Participants with Wet AMD -

- ODYSSEY Topline Results Expected in Q3 2024 -

ALPHARETTA, Ga., June 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 that enrollment has opened in ODYSSEY, its Phase 2b clinical trial of CLS-AX (axitinib injectable suspension) using suprachoroidal delivery in neovascular age-related macular degeneration (wet AMD).

“With the ODYSSEY clinical trial now open for enrollment, we are excited to continue exploring the potential of CLS-AX to provide an effective and less burdensome treatment option in the multi-billion-dollar wet AMD market,” said George Lasezkay, Pharm.D., J.D., Clearside’s President and Chief Executive Officer. “CLS-AX will be delivered via our patented SCS® Microinjector giving us unprecedented access to the back of the eye to directly target the site of the disease behind the visual field. We believe that our potent and well-tolerated tyrosine kinase inhibitor (TKI) combined with targeted suprachoroidal delivery has the potential to produce promising results in our Phase 2 clinical trial.”

“Our primary goals for ODYSSEY are to maintain visual acuity and demonstrate improved duration with reduced treatment burden for the CLS-AX arm. We believe that the number of participants, duration, and outcome measures of the study will provide the necessary clinical data to design a CLS-AX Phase 3 program. We are targeting a total of 30 U.S. based clinical trial sites for ODYSSEY and expect to report topline data from the trial in the third quarter of next year,” concluded Dr. Lasezkay.

About the ODYSSEY Phase 2b Clinical Trial

ODYSSEY is a randomized, double-masked, parallel-group, active-controlled, multi-center, Phase 2b clinical trial of 36 weeks duration.

- Number of Participants: 60 total participants with 2:1 randomization.
  - 40 participants in CLS-AX arm and 20 participants in aflibercept arm.
- Key inclusion criteria:
  - Diagnosed with wet AMD within 36 months of screening.
  - History of 2 to 4 anti-VEGF treatments in the 6 months before screening.
  - History of response to anti-VEGF treatment for wet AMD.
  - Reading center confirmation of persistent active disease.
  - Best corrected visual acuity (BCVA) of 20 to 80 letters
- Treatment Protocol:
  - Loading Doses: Participants in both arms will receive three monthly aflibercept (2 mg) loading doses. At the second loading dose (Baseline visit), participants in the CLS-AX arm will receive one dose of CLS-AX (1.0 mg).
  - Disease Activity Assessments (DAA): Conducted monthly in both arms at Weeks 12 through 32 to determine if there is a need for supplemental treatment.
  - Aflibercept arm (per approved label): Participants will receive aflibercept on a fixed dosing regimen every 8 weeks. If needed based on DAA, aflibercept may be given at the 4-week interval as supplemental treatment.
  - CLS-AX Arm: Participants will receive CLS-AX at Week 24, if they have not received a second dose since the Baseline visit. If needed based on DAA, CLS-AX may be given 12 weeks after the last dose. If less than 12 weeks, aflibercept may be given as supplemental treatment.
- Supplemental treatment criteria (based on measurement changes due to wet AMD):
  - BCVA reduction of >10 letters from Baseline.
  - Increase in central subfield thickness (CST) of >100 microns on SD-OCT from Baseline.
  - BCVA reduction of > 5 letters from Baseline AND increase in CST of >75 microns on SD-OCT from Baseline.
  - Presence of new or worsening vision-threatening hemorrhage.
- Primary outcome measure: Mean change in BCVA from Baseline to Week 36.
- Secondary outcome measures:
  - Other changes in visual function and ocular anatomy, such as CST.
  - Need for supplemental treatment.
  - Treatment burden as measured by total injections over trial duration.

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 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].

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 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 2 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 www.clearsidebio.com.

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.

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 number of sites for the ODYSSEY Phase 2b clinical trial for 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 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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