



## **Clearside Biomedical Completes Dosing in OASIS Phase 1/2a Clinical Trial of CLS-AX (axitinib injectable suspension) in Wet AMD Patients**

July 26, 2022

*- CLS-AX Dosing Completed in Cohorts 3 and 4 -*

*- Final OASIS Data Expected in Q4 2022 -*

ALPHARETTA, Ga., July 26, 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<sup>®</sup>), announced today completion of dosing in Cohorts 3 and 4 of OASIS, its Phase 1/2a clinical trial of CLS-AX (axitinib injectable suspension) in patients with neovascular age-related macular degeneration (wet AMD).

OASIS is a U.S.-based, multi-center, open-label, dose-escalation trial in wet AMD patients to assess the safety and tolerability of a single dose of CLS-AX administered by suprachoroidal injection. The study enrolled 8 patients in Cohort 3 and 8 patients in Cohort 4, all of whom received aflibercept at their first visit and a single dose of CLS-AX at their second visit one month later. In total, there were 27 patients in four cohorts enrolled in OASIS, with escalating doses of CLS-AX (in mg): Cohort 1 at 0.03 (n=6); Cohort 2 at 0.10 (n=5); Cohort 3 at 0.50 (n=8); Cohort 4 at 1.0 (n=8). The primary endpoint for the trial will assess the safety and tolerability of CLS-AX for three months following the administration of CLS-AX. There is also an ongoing extension study to follow patients in Cohorts 2, 3 and 4 for three months after their completion of OASIS.

"We look forward to providing more data on the potential benefits of combining targeted and compartmentalized suprachoroidal delivery via our SCS Microinjector<sup>®</sup> with the broad pan-VEGF attributes of axitinib," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer and Chief Development Officer. "The completion of enrollment in OASIS is a critical milestone as we look forward to our data readout from the full OASIS trial in the fourth quarter of this year. We are grateful to all our investigators and patients whose time and commitment made this first-in-human, suprachoroidal tyrosine kinase inhibitor trial possible."

### **OASIS Phase 1/2a Clinical Trial Design**

OASIS is an open-label, dose-escalation Phase 1/2a trial in wet AMD patients to assess the safety and tolerability of a single dose of CLS-AX administered by suprachoroidal injection via Clearside's SCS Microinjector<sup>®</sup>. Eligible patients are those who demonstrate stable visual acuity following two or more previous injections with an intravitreal anti-VEGF agent. All enrolled patients undergo diagnostic imaging at their screening, followed by masked reading center confirmation of persistent active disease.

Enrolled patients initially receive aflibercept at the first visit followed by a single dose of CLS-AX at the second visit one month later. The primary endpoint for the trial will assess the safety and tolerability of CLS-AX for the three months following the administration of CLS-AX, and secondary endpoints will evaluate the pharmacokinetics, visual function, ocular anatomy, and the need for additional treatment with intravitreal aflibercept during the three-month period. Additional information on the Phase 1/2a trial can be found on <https://clinicaltrials.gov> (NCT04626128).

### **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 to treat renal cell cancer 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. Preclinical results from Clearside and independent investigators have shown pharmacodynamic effects with reduced growth of experimental neovascularization and decreased fluorescein leakage. With suprachoroidal administration of axitinib, there is the potential to achieve prolonged duration and targeted delivery to affected tissue layers to potentially treat VEGF-driven disorders such as wet AMD, diabetic macular edema and diabetic retinopathy.

### **About Neovascular Age-Related Macular Degeneration (wet 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. 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, and about 20% have the wet form. 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.

### **About Clearside's Suprachoroidal Space (SCS<sup>®</sup>) Injection Platform and SCS Microinjector<sup>®</sup>**

Clearside's patented, proprietary suprachoroidal space (SCS<sup>®</sup>) injection platform offers unprecedented access to the back of the eye where sight-threatening disease often occurs. Clearside's patented technology is designed to deliver drug to the suprachoroidal space located between the choroid and the outer protective layer of the eye, known as the sclera. The company's unique platform is inherently flexible and intended to work with established and new formulations of medications. Clearside's proprietary SCS Microinjector can be used to inject a wide variety of drug candidates into the SCS. The SCS Microinjector provides targeted delivery to potentially improve efficacy and compartmentalization of medication to reduce or

eliminate toxic effects on non-diseased cells. The SCS Microinjector is composed of a syringe and two 30-gauge hollow microneedles of varying lengths, each less than 1.2 millimeters, within a custom-designed hub that optimizes insertion and suprachoroidal administration of drugs.

### **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<sup>®</sup>). Clearside's SCS injection platform, utilizing the Company's proprietary SCS Microinjector<sup>®</sup>, 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<sup>®</sup>](#) (triamcinolone acetonide injectable suspension) for suprachoroidal use, is commercially available in the U.S. For more information, please visit [www.clearsidebio.com](http://www.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, including the expected timing of data from the OASIS clinical trial, and the potential benefits of CLS-AX. 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, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission (SEC) on March 11, 2022, 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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