Clearside Biomedical Announces First Patients Enrolled in Phase 1/2a Clinical Trial of CLS-AX (axitinib injectable suspension) for the Treatment of Wet AMD

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ALPHARETTA, Ga., Jan. 12, 2021 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases, announced today that the first patients have been enrolled in its Phase 1/2a clinical trial of CLS-AX (axitinib injectable suspension) in patients with neovascular age-related macular degeneration (wet AMD). Clinical sites, all based in the United States, are activated and currently screening wet AMD patients for this Phase 1/2a trial, known as OASIS, involving CLS-AX, a proprietary suspension of axitinib for suprachoroidal injection.

“The enrollment of the first patients for our OASIS trial is a key milestone for Clearside as we execute our strategy to expand our ophthalmology pipeline with innovative and relevant opportunities targeting critical medical needs through the suprachoroidal space (SCS®),” said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. “We believe that axitinib, a small molecule tyrosine kinase inhibitor (TKI), could provide safety and efficacy comparable to, or better than, current standard of care. And by delivering axitinib as a suspension into the suprachoroidal space using our in-office, non-surgical SCS Microinjector®, we may potentially extend the duration of therapeutic action and reduce or relieve the profound treatment burden for wet AMD patients. We expect data from our first cohort of patients in mid-2021.”

OASIS is a Phase 1/2a open-label, dose-escalation study in wet AMD patients to assess the safety and tolerability of a single dose of CLS-AX administered by suprachoroidal injection. Eligible patients are those who demonstrate stable visual acuity following two or more previous injections with an intravitreal anti-VEGF agent. 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.

The study design consists of 3 cohorts of 5 patients each (n=15). Cohort 1 participants will receive the lowest dose, 0.03 mg of axitinib delivered via suprachoroidal injection. Dose escalation will then proceed following review of the safety data by the Safety Monitoring Committee and their recommendation to advance to the next higher dose cohort. Additional information on the Phase 1/2a trial can be found on https://clinicaltrials.gov (NCT04626128).

In preclinical studies, CLS-AX delivered suprachoroidally was observed to be well tolerated and showed significant ocular tissue concentrations over time. These characteristics, if demonstrated clinically, may support the potential for suprachoroidal axitinib to reduce or relieve the treatment burden for patients suffering from wet AMD.

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. Clearside is developing CLS-AX as a long-acting therapy for the treatment of wet AMD. CLS-AX is currently in a Phase 1/2a clinical trial and additional information can be found on https://clinicaltrials.gov (NCT04626128).

About Clearside’s Suprachoroidal Space (SCS ®) Injection Platform

Clearside’s patented, proprietary suprachoroidal space (SCS) injection treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. Clearside’s proprietary SCS Microinjector ® can be used to inject a wide variety of drug candidates that are specifically formulated to be delivered via suprachoroidal injection. Clearside’s unique platform is inherently flexible and intended to work with certain established medications, new formulations of small molecule medicines, as well as future innovations such as gene therapy.

About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases. Clearside’s proprietary SCS Microinjector ® targets the suprachoroidal space (SCS®) and offers unique access to the macula, retina and choroid where sight-threatening disease often occurs. Clearside’s SCS injection platform is an inherently flexible, in-office, non-surgical procedure, intended to provide targeted delivery to the site of disease and to work with both established and new formulations of medications, as well as future therapeutic innovations such as gene therapy. For more information, please visit 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 development and potential benefits of CLS-AX and the timing of data from the Phase 1/2a clinical trial for CLS-AX in wet AMD. 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, 2019, filed with the U.S. Securities and Exchange Commission ("SEC") on March 13, 2020, Clearside's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 10, 2020 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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