Clearside Biomedical Announces CLS-AX (axitinib injectable suspension) Presentation Delivered at Angiogenesis, Exudation, and Degeneration 2021 Program

February 16, 2021

ALPHARETTA, Ga., Feb. 16, 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 David M. Brown, M.D. delivered a presentation entitled, “Axitinib: A Novel TKI Delivered by Suprachoroidal Injection for AMD” at the virtual Angiogenesis, Exudation, and Degeneration 2021 program hosted by the University of Miami Health System Bascom Palmer Eye Institute on February 12 & 13, 2021.

Dr. Brown’s presentation highlighted several of the key attributes of axitinib and Clearside’s suprachoroidal delivery of the agent, including the ease of administration as demonstrated in a video of a clinical trial patient undergoing the office-based suprachoroidal delivery procedure. In preclinical studies, axitinib showed intrinsic high potency, pan-VEGF inhibition through receptor blockade versus focused VEGF-A inhibition seen in currently marketed anti-VEGF treatments. Axitinib is a highly potent tyrosine kinase inhibitor (TKI) that has been observed preclinically to be greater than ten times more potent than other TKIs, and inhibits and regresses angiogenesis.

Suprachoroidal delivery of Clearside’s proprietary, injectable suspension of axitinib, known as CLS-AX, has produced up to eleven times higher drug levels in affected tissues than intravitreal administration of axitinib in preclinical models. This compartmentalized delivery to affected posterior tissues may minimize treatment related adverse events, such as vitreous floaters and corneal and anterior segment exposure. With the prolonged duration observed in pharmacokinetic studies, this targeted treatment approach also has the potential to reduce treatment burden for patients.

“We appreciate Dr. Brown’s thorough presentation which highlighted the potential of axitinib and CLS-AX to improve the treatment landscape for the millions of patients suffering from wet AMD,” said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer and Chief Development Officer. “By combining the high potency and pan-VEGF attributes of axitinib with our proprietary CLS-AX formulation and delivery via our SCS Microinjector®, we believe we can achieve clinical adoption of this technique by the retina community and improve the overall patient experience with a longer lasting treatment that may reduce or eliminate the challenging side effects seen with other agents. Our Phase 1/2a OASIS clinical trial in wet AMD is an ongoing US-based, multi center, open-label, dose-escalation, safety and tolerability study. We expect to report initial safety data from the first OASIS cohort mid-year 2021.”

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 being investigated in an ongoing US-based, multi-center, open-label, dose-escalation, Phase 1/2a, safety and tolerability study, entitled OASIS, in wet AMD patients, and additional information can be found on https://clinicaltrials.gov (NCT04626128).

About Clearside’s SCS Microinjector ®

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. 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 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. The Company’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 clinical development, including the timing of safety data from the OASIS clinical trial, and the potential benefits, of CLS-AX

and therapies 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, 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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Source: Clearside Biomedical, Inc.