Clearside Biomedical Announces U.S. FDA Acceptance of Investigational New Drug Application for CLS-AX (axitinib injectable suspension) Administered in Suprachoroidal Space

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- Initiation of CLS-AX Phase 1/2a Clinical Trial in Wet AMD Targeted by Year-End 2020 -

ALPHARETTA, Ga., Aug. 10, 2020 (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 U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for CLS-AX (axitinib injectable suspension), enabling initiation of a Phase 1/2a clinical trial of CLS-AX in neovascular age-related macular degeneration (wet AMD) patients by the end of 2020.

“The FDA’s acceptance of our IND submission for CLS-AX is a significant achievement for Clearside and demonstrates our ability to successful move another internally-developed program into the clinic,” said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. “As a tyrosine kinase inhibitor (TKI), axitinib has demonstrated pan-VEGF inhibition in independent studies and may have the potential to be more efficacious than current, more narrowly focused VEGF inhibition approaches. In our internal preclinical studies, CLS-AX delivered through suprachoroidal injection was well tolerated and showed durability over several months, providing Clearside the opportunity to potentially reduce treatment burden and address a primary need for wet AMD patients. We look forward to initiating clinical work by the end of 2020.”

The Phase 1/2a clinical trial in wet AMD patients is expected to be an open-label, dose-escalation study to assess the safety and tolerability of single doses of CLS-AX administered through suprachoroidal injection following two or more prior treatments with an intravitreal anti-VEGF agent.

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 effect 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.

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 timing of initiating the Phase 1/2a clinical trial for CLS-AX in wet AMD and the potential benefits of CLS-AX and the 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 filed with the SEC on May 8, 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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