Clearside Biomedical's Oncology Licensing Partner Doses First Patient in its Phase 2 Study in Patients with Choroidal Melanoma Using SCS Microinjector® for Suprachoroidal Delivery

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ALPHARETTA, Ga., Sept. 11, 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 its licensing partner, Aura Biosciences, has dosed the first patient in its Phase 2 clinical trial evaluating the safety and efficacy of suprachoroidal administration of AU-011 as a potential first-line treatment for patients with primary choroidal melanoma. Aura is using Clearside's SCS Microinjector ® to deliver AU-011 into the suprachoroidal space (SCS®).

Aura also announced that AU-011 passed the Safety Review for the first dose escalation cohort which demonstrated favorable safety data with no safety findings and no adverse events noted. Aura's preclinical data on suprachoroidal injection of AU-011 presented at the Association for Research in Vision and Ophthalmology conference can be accessed here.

"With this trial initiation, we are on track to have three product candidates delivered via our SCS Microinjector in four clinical trials this year," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer and Chief Development Officer. "Choroidal melanoma is a rare and aggressive type of eye cancer and is the most common primary intraocular tumor in adults. Aura is a leader in their field and there is an unmet need for a new first-line treatment option for early stage choroidal melanoma. We are excited by ocular oncologists' interest in suprachoroidal delivery and look forward to Aura's continued progress."

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 and the potential benefits of therapies using Clearside's SCS Microinjector ® and the timing of data presentations by Clearside's licensing partner. 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 June 30, 2020, filed with the SEC on August 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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