Clearside Biomedical Announces Data Presentations at the American Academy Ophthalmology (AAO) 2020 Annual Meeting and Publication on the Suprachoroidal Injection Procedure in Translational Vision Science and Technology

November 16, 2020

ALPHARETTA, Ga., Nov. 16, 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 two presentations of Clearside preclinical and clinical data were given at the virtual American Academy Ophthalmology (AAO) 2020 Annual Meeting.

Clearside also announced a clinical characterization of the suprachoroidal injection procedure across three retinal disorders was published in the Association for Research in Vision and Ophthalmology (ARVO) peer-reviewed, Medline-indexed journal, *Translational Vision Science and Technology*, which can be accessed here. The data described in this paper demonstrate that suprachoroidal injection was well accepted by physician-investigators, and that the device and procedure may accommodate a wide range of anatomic and demographic variables. These data suggest that suprachoroidal injection could be readily adopted in clinical practice for targeted, compartmentalized delivery of ocular therapies.

"Reflecting on the past year, I am grateful to our team and the numerous physicians and researchers who have delivered 33 presentations on our assets and suprachoroidal space (SCS®) injection platform during 2020," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer and Chief Development Officer. "In addition to our conference presentations, we have placed four publications in peer reviewed journals to further educate the medical community on our clinical progress. This coverage and attention on our programs have established Clearside as the leader in suprachoroidal delivery. We look forward to continuing to advance our suprachoroidal delivery programs with data expected in 2021 from our CLS-AX (axitinib injectable suspension) Phase 1/2a clinical trial, and our integrin inhibitor preclinical studies."

Dr. Ciulla continued, "In addition to our internal progress, we are pleased with the advancements of our clinical development partners. This weekend at the AAO conference, suprachoroidal delivery was featured by our gene therapy partner, REGENXBIO, as well as in a late breaking presentation from Aura Biosciences in choroidal melanoma. Both of these companies are using our SCS Microinjector® to deliver their assets into the suprachoroidal space."

Title: Suprachoroidal CLS-AX (axitinib injectable suspension), as a Potential Long-Acting Therapy for Neovascular Age-Related Macular Degeneration (nAMD)
Authors: Robert Bhisitkul; Viral Kansara; Thomas Ciulla
Conclusions:
CLS-AX is intended to be a targeted therapy to affected tissue layers via suprachoroidal injection. Axitinib has intrinsic high potency and pan-VEGF inhibition through receptor blockade. In pharmacokinetic studies, CLS-AX demonstrated prolonged duration. The U.S. Food and Drug Administration has accepted Clearside's Investigational New Drug Application and a Phase 1/2a clinical trial in wet age-related macular degeneration (wet AMD) is expected to initiate by the end of 2020.

Title: Systemic Therapy and Efficacy of CLS-TA: Results from the Phase 3 PEACHTREE Clinical Trial
Authors: Quan Nguyen; Thomas Ciulla
Conclusions: These post hoc results corroborate the pre-specified study analyses in the PEACHTREE trial. The visual acuity and macular edema improvements associated with suprachoroidally injected CLS-TA versus the control in treating macular edema associated with noninfectious uveitis, was noted regardless of administration of systemic therapy at baseline.

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 established medications, new formulations of medicines, as well as future innovations such as gene therapy.

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 XIPERE ™(triamcinolone acetonide suprachoroidal injectable suspension)

XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye and being investigated for the treatment of macular edema

associated with non-infectious uveitis. 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. Suprachoroidal injection enables the rapid and adequate dispersion of medicine to the back of the eye, offering the potential for the medicine to act longer and minimize harm to the surrounding healthy parts of the eye. Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc. ("Bausch Health") (NYSE/TSX: BHC), has the exclusive license for the commercialization and development of XIPERE in the United States and Canada and exclusive options for the right to commercialize and develop XIPERE in Europe and the United Kingdom, Australia and New Zealand, and South America and Mexico (through a license agreement between Clearside and Bausch Health's affiliate). Arctic Vision, a specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE in Greater China and South Korea.

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 XIPERE, including the timing of initiation of and data from the Phase 1/2a clinical trial for CLS-AX in wet AMD, as well as the timing of data from preclinical studies in Clearside's integrin inhibitor program. 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.