Clearside Biomedical's Phase 1/2 Open Label Clinical Trial of CLS-TA With and Without Eylea in Diabetic Macular Edema Presented at the American Academy of Ophthalmology 2017 Annual Meeting

November 13, 2017

ALPHARETTA, Ga., Nov. 13, 2017 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a late-stage clinical biopharmaceutical company developing first-in-class drug therapies to treat back-of-the-eye diseases, announced that, on Friday, November 10, 2017, during the Retina Subspecialty Day of the American Academy of Ophthalmology 2017 Annual Meeting ("AAO 2017") in New Orleans, LA, Charles C. Wykoff , MD, PhD, presented preliminary results from an exploratory clinical trial (the "HULK trial") of CLS-TA, Clearside's proprietary suspension formulation of the corticosteroid triamcinolone acetonide for suprachoroidal administration ("suprachoroidal CLS-TA"), with and without intravitreally injected EYLEA® (aflibercept) ("intravitreal Eylea") for the treatment of diabetic macular edema ("DME").

DME is the most common cause of vision loss in people with diabetes mellitus. A consequence of diabetic retinopathy, DME is swelling of the retina caused by leaking blood vessels. DME affects up to 30% of people who have had diabetes for 20 years or more, and if untreated, approximately 20 to 30% of people who have it will experience moderate visual loss.

In April 2017, Clearside completed patient enrollment in the HULK trial, an open-label, multicenter Phase 1/2 clinical trial designed to assess the safety and efficacy of suprachoroidal CLS-TA in combination with intravitreal Eylea in 10 patients with DME who are naïve to treatment. The trial is also assessing the safety and efficacy of suprachoroidal CLS-TA alone in 10 patients with DME who have previously been treated with intravitreal anti-VEGF agents or intravitreal corticosteroids and still require further treatment.

The HULK trial findings presented by Dr. Wykoff at AAO 2017 showed a visual benefit for patients receiving CLS-TA, with a greater benefit in treatment naïve eyes. Anatomic improvement was observed in all treated eyes, with more than two-thirds of those eyes achieving a greater than 50% reduction in excess central retinal thickness based on monthly measurements through 6 months after initial treatment. In the treatment naïve group, 40% of patients did not require retreatment over the entire 6 months, with an additional 20% requiring only one retreatment. Suprachoroidal CLS-TA, including in patients who received as many as five injections, was well tolerated, with a low incidence of ocular side effects, including IOP elevations.

Dr. Wykoff commented, "While the current standard of care most commonly used to treat patients with DME is use of intravitreal anti-VEGF agents, there is still a significant unmet need in this large patient population. These initial results from the HULK study suggest encouraging efficacy with a trend toward durability, particularly in the combination treatment arm."

"We believe that eye complications associated with diabetes are caused by multiple pathways," commented Dr. Richard Beckman, Chief Medical Officer of Clearside. "As a result, even with repeated monthly injections for six months, approximately 40% of DME patients have an insufficient response to treatment with anti-VEGF agents alone. We believe that suprachoroidal CLS-TA, used together with an intravitreal anti-VEGF agent, has the potential to improve treatment outcomes and reduce the treatment burden for newly diagnosed DME patients, as both corticosteroids and anti-VEGF agents have been shown to be effective in the treatment of DME. To that end, we are completing patient follow-up in our TYBEE trial, a controlled, randomized, masked Phase 2 clinical trial of CLS-TA used together with Eylea in patients who are naïve to treatment for their DME, and expect to release preliminary data from this trial in the second quarter of 2018."

Suprachoroidal CLS-TA, used either alone or together with an intravitreal anti-VEGF agent, is being studied as part of Clearside's pipeline for the treatments of unmet or underserved blinding eye diseases where the pathologies manifest in the choroid and retina.

About Clearside

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a late-stage clinical ophthalmic biopharmaceutical company that envisions a world without blindness. Clearside relentlessly pursues transformative, elegant, precise solutions to restore and preserve vision. Clearside is developing advanced clinical and preclinical product candidates using a proprietary treatment approach offering unprecedented access to the back of the eye through the suprachoroidal space (SCS™). This offers potentially meaningful treatment benefit to patients suffering from sight threatening diseases like uveitis, RVO, diabetic macular edema and wet age-related macular degeneration. CLS-TA for suprachoroidal administration, used either alone or together with an intravitreal anti-VEGF agent, is part of Clearside's pipeline for the treatments of unmet or underserved blinding eye diseases where the pathologies manifest in the choroid and retina. To learn more about how Clearside is changing ophthalmology, please visit us at 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 expectations regarding the clinical development of, and the potential market for, Clearside's product candidates and the availability of data from Clearside's clinical trials. 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, and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2016, filed with the U.S. Securities and Exchange Commission ("SEC") on March 16, 2017, 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.

Contacts:

Stephen Kilmer
Investor Relations
(678) 270-3631
stephen.kilmer@clearsidebio.com

Charles Deignan

Chief Financial Officer
(678) 270-4005
charlie.deignan@clearsidebio.com

Source: Clearside Biomedical, Inc.