Clearside Biomedical, Inc. Announces Completion of Patient Enrollment in Phase 1/2 Open Label Clinical Trial of CLS-TA in Diabetic Macular Edema

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Company Completing Preparations to Initiate Phase 2 Trial in Mid-2017

ALPHARETTA, Ga., April 20, 2017 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (Nasdaq:CLSD), a late-stage biopharmaceutical company developing first-in-class drug therapies to treat back-of-the-eye diseases, today announced completion of enrollment of an exploratory clinical trial (the "HULK" trial) of CLS-TA for suprachoroidal administration, its proprietary suspension formulation of the corticosteroid triamcinolone acetonide, with or without intravitreal Eylea® (aflibercept), for the treatment of diabetic macular edema ("DME").

The HULK trial is an open-label, multi-center Phase 1/2 study designed to assess the safety and efficacy of the administration of a suprachoroidal injection of CLS-TA along with an intravitreal injection of Eylea in patients with DME naïve to treatment, as well as that of a suprachoroidal injection of CLS-TA alone in patients with DME who have previously been treated with intravitreal anti-VEGF or intravitreal corticosteroid treatment and still require further treatment. Clearside currently expects to report preliminary results from the HULK trial in the second half of 2017.

"While the current standard of care in treating patients with DME is through the use of intravitreally delivered anti-VEGF agents, a significant unmet need remains in this large patient population. Approximately 40% of DME patients have an insufficient response to VEGF inhibitors. We believe that, by administering suprachoroidal CLS-TA with the potential to access the retina and choroid in high amount, concomitantly with intravitreal Eylea, there is the opportunity to more effectively treat DME when compared with current intravitreal anti-VEGF or corticosteroid therapies used alone," said Daniel H. White, Chief Executive Officer and President of Clearside. "I would like to take this opportunity to thank the participating physicians and patients in the HULK trial, and to congratulate our team for working so diligently and effectively to complete study enrollment with the goal of addressing the needs of these patients. We are also in the process of final preparations to initiate a larger Phase 2 trial in this blinding eye disease."

Clearside currently expects to enroll the first patient in the planned multicenter, randomized, masked, controlled Phase 2 trial (the "TYBEE" trial) in mid-2017. TYBEE will evaluate suprachoroidal CLS-TA along with intravitreal Eylea, compared to intravitreal Eylea only, in patients with DME, over a 6-month evaluation period. The primary endpoint of the trial will be the change in best corrected visual acuity from baseline in the combination treatment arm compared to the intravitreal Eylea only arm.

Suprachoroidal CLS-TA, 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.

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 pre-clinical 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, retinal vein occlusion, DME and wet age-related macular degeneration. 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. 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

Clearside Biomedical, Inc.