Clearside Biomedical Announces First Patient Randomized in Phase 2 Clinical Trial of CLS-TA Used Together with Eylea in Patients with Diabetic Macular Edema

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ALPHARETTA, Ga., July 11, 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 the enrollment of the first patient in a phase 2 clinical trial ("TYBEE") of CLS-TA for suprachoroidal administration ("suprachoroidal CLS-TA"), Clearside's proprietary suspension formulation of the corticosteroid triamcinolone acetonide, used together with intravitreally administered EYLEA® (aflibercept) ("intravitreal Eylea") for the treatment of diabetic macular edema ("DME").

TYBEE is a multicenter, randomized, masked, controlled phase 2 clinical trial designed to evaluate the safety and efficacy of suprachoroidal CLS-TA along with intravitreal Eylea, compared to intravitreal Eylea monotherapy, in patients with DME who are naïve to pharmacologic treatment. In this trial, patients with DME will be randomized into either a combination arm of patients receiving suprachoroidal CLS-TA together with intravitreal Eylea or a control arm of patients receiving only intravitreal Eylea. The primary outcome measure will be a comparison between the two study arms of change from baseline in best corrected visual acuity at 3 months.

"We believe that eye complications associated with diabetes are caused by multiple pathways in this difficult to treat disease, and that we can improve the visual outcomes for newly diagnosed DME patients by administering suprachoroidal CLS-TA together with an intravitreal anti-VEGF inhibitor like Eylea," said Daniel H. White, Chief Executive Officer and President of Clearside. "The enrollment of the first patient in the TYBEE trial represents an important step forward in Clearside's DME clinical development program and we currently expect to report three-month preliminary data in the first half of 2018."

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.

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, 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 Clearside's product candidates and the timing of preliminary data from Clearside's TYBEE trial. 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.

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