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

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ALPHARETTA, Ga., Oct. 24, 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 patient enrollment in the Phase 2 clinical trial ("TYBEE") of CLS-TA, Clearside's proprietary suspension formulation of the corticosteroid triamcinolone acetonide for suprachoroidal administration ("suprachoroidal CLS-TA"), used together with intravitreally administered EYLEA® (aflibercept) ("intravitreal Eylea") for the treatment of diabetic macular edema ("DME"). Patient follow-up in the TYBEE trial is 6 months.

DME is the most common cause of vision loss in people with diabetes mellitus. A consequence of diabetic retinopathy, DME is swelling in the area of the retina called the macula 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.

The TYBEE trial, a multicenter, randomized, masked, controlled Phase 2 trial, has enrolled 71 patients who are naïve to pharmacologic treatment for DME. In this trial, patients were randomized into either a combination arm to receive suprachoroidal CLS-TA together with intravitreal Eylea or a control arm to receive only intravitreal Eylea. The primary outcome measure is a comparison of mean change from baseline in best corrected visual acuity between the two study arms. An additional analysis will be a comparison between the number of injections required between the two groups.

"The completion of patient enrollment in the TYBEE trial represents an important milestone and step forward in our DME clinical development program. We have eclipsed over 300 patients who have been treated for sight threatening diseases with suprachoroidal CLS-TA," said Daniel H. White, Chief Executive Officer and President of Clearside. "We believe that eye complications associated with diabetes are caused by multiple pathways and, despite the use of anti-VEGF drugs, there remains a significant unmet need. Even with repeated monthly injections for six months, approximately 40% of DME patients have an insufficient response to treatment. We believe that we can improve the visual outcomes for newly diagnosed DME patients by administering suprachoroidal CLS-TA together with an intravitreal anti-VEGF inhibitor because both corticosteroids and anti-VEGF agents have been shown to be effective in the treatment of DME."

CLS-TA for suprachoroidal administration, 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 nonclinical 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 potential attributes and benefits of 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.

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