Clearside Biomedical, Inc. Announces First Patient Randomized in Phase 3 Clinical Trial of Zuprata™ Used Together With Eylea in Subjects With Retinal Vein Occlusion

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ALPHARETTA, Ga., Feb. 16, 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 3 clinical trial ("SAPPHIRE") of Zuprata™, its proprietary suspension formulation of the corticosteroid triamcinolone acetonide, used together with EYLEA® (aflibercept) for the treatment of macular edema associated with retinal vein occlusion ("RVO").

SAPPHIRE is a multicenter, randomized, masked, controlled trial to assess the efficacy and safety of suprachoroidally administered Zuprata ("suprachoroidal Zuprata") used together with intravitreally administered Eylea ("intravitreal Eylea") in subjects with RVO. Patients in the combination treatment arm will receive suprachoroidal Zuprata together with intravitreal Eylea at the beginning of the trial, intravitreal Eylea alone at week 4, and suprachoroidal Zuprata together with intravitreal Eylea at weeks 12 and 24. Patients in the control arm will receive intravitreal Eylea alone at the beginning of the trial and follow-up treatments of intravitreal Eylea alone every four weeks through week 24. After 24 weeks, patients will be followed for approximately an additional six months. The primary objective of this trial will be to determine the proportion of patients in each arm with a best corrected visual acuity improvement of at least 15 letters from baseline at eight weeks after initial treatment. There will be several secondary efficacy and safety endpoints that will also be evaluated. Clearside anticipates total enrollment of approximately 460 patients in the trial.

"This patient's enrollment represents another significant milestone in our Zuprata development program," said Daniel H. White, Clearside's Chief Executive Officer and President. "Based on the visual acuity improvements and macular edema reductions observed in its previous Phase 2 TANZANITE trial, we believe the SAPPHIRE study has the potential to demonstrate that the addition of Zuprata to Eylea treatment may offer an earlier opportunity for improved vision and reduction of macular edema over Eylea treatment alone. We believe that when Zuprata is used together with intravitreal Eylea in RVO patients, it has the potential to provide similar vision results with fewer injections."

Suprachoroidal Zuprata used together with intravitreal Eylea for RVO is part of Clearside's pipeline of drug treatments for unmet or underserved blinding eye diseases where the pathologies manifest in the choroid or retina.

About Retinal Vein Occlusion

RVO is a sight-threatening disorder resulting from a blockage of one or more of the veins carrying blood out of the retina. This blockage can lead to bleeding within the retina and the additional fluid can cause swelling resulting in macular edema. This bleeding and macular edema can affect central vision. According to a 2010 study published in the journal *Ophthalmology*, RVO is estimated to affect more than 16 million adults worldwide. Of those, Clearside estimates approximately 2.2 million reside in the United States.

About Clearside

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a publicly traded, ophthalmic biopharmaceutical company that envisions a world without blindness. Clearside relentlessly pursues transformative, elegant, precise solutions to restore and preserve vision. Clearside is developing therapies for eye diseases using a proprietary treatment approach offering unprecedentedly high access for the pharmacological candidates to the back of the eye through suprachoroidal injection. This new treatment paradigm offers potentially meaningful therapeutic benefit to patients suffering from sight threatening diseases like uveitis, RVO, diabetic macular edema and wet AMD. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the U.S. Securities and Exchange Commission ("SEC") on November 14, 2016 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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