Clearside Biomedical Announces Completion of Patient Enrollment in Pivotal Phase 3 PEACHTREE Clinical Trial of CLS-TA for Suprachoroidal Administration in Patients with Macular Edema Associated with Non-Infectious Uveitis

August 7, 2017

Clearside Expects to Report Top-Line Results in Q1-2018

ALPHARETTA, Ga., Aug. 07, 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 pivotal PEACHTREE clinical trial. This Phase 3 clinical trial is evaluating the safety and efficacy of CLS-TA for suprachoroidal administration ("suprachoroidal CLS-TA"), Clearside's proprietary suspension formulation of the corticosteroid triamcinolone acetonide, for the treatment of macular edema associated with non-infectious uveitis. Patient follow-up in the PEACHTREE trial is 6 months. Accordingly, Clearside currently expects to report top-line results from the trial in the first quarter of 2018.

Uveitis, a set of inflammatory conditions affecting the eye, is one the world's leading causes of blindness. Uveitis occurs in about 350,000 patients in the United States and is typically found in both eyes. Macular edema occurs in approximately one-third of all non-infectious uveitis cases and is a major contributor to vision loss in these patients.

The PEACHTREE trial, a randomized, masked, sham-controlled Phase 3 trial, has enrolled 160 patients with macular edema associated with non-infectious uveitis. The primary efficacy outcome measure in the trial is based on improvement in best corrected visual acuity over the 6-month duration of the clinical trial. Safety will be assessed by analyzing the occurrence of adverse events and changes in key safety parameters over the course of the trial. Additional efficacy and safety endpoints will also be evaluated. Based on feedback from its end-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") held in May 2015, Clearside believes that PEACHTREE will be the only Phase 3 clinical trial required to support the potential filing of a New Drug Application, or NDA, with the FDA.

"CLS-TA for the treatment of non-infectious uveitis is our most advanced clinical development program, and completion of patient enrollment in the Phase 3 PEACHTREE trial marks the achievement of a major milestone for our company," said Daniel H. White, Chief Executive Officer and President of Clearside. "Non-infectious uveitis, despite current therapy, is still a leading cause of vision loss throughout the world. With the completion of enrollment is this Phase 3 trial, Clearside is making a giant step toward potentially offering a dynamic new treatment for patients."

As previously reported, Clearside's Phase 2 DOGWOOD trial of suprachoroidal CLS-TA in patients with non-infectious uveitis met its primary endpoint, with a statistically significant mean reduction from baseline in retinal thickness of 164 microns at eight weeks following dosing (p=0.002). There was also a statistically significant mean 9 letter improvement in best corrected visual acuity at eight weeks following dosing (p=0.0004).

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 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, diabetic macular edema 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, the potential attributes and benefits of Clearside's product candidates and the timing of top-line results from Clearside's PEACHTREE 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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