Clearside Biomedical Announces Completion of Patient Enrollment in First of Two Phase 3 Clinical Trials of CLS-TA in Retinal Vein Occlusion

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ALPHARETTA, Ga., June 13, 2018 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases, today announced completion of patient enrollment in a Phase 3 clinical trial ("SAPPHIRE") of suprachoroidal CLS-TA used in combination with intravitreally administered EYLEA® (aflibercept) ("intravitreal Eylea") for the treatment of Retinal Vein Occlusion ("RVO").

RVO is a particularly aggressive eye disease resulting from an occlusion in a vein carrying blood out of the retina. This blockage can lead to the rapid onset of symptoms, including sudden declines in vision. SAPPHIRE, a multicenter, multi-country, randomized, masked, controlled Phase 3 clinical trial, has enrolled 460 patients who are naïve to pharmacologic treatment for RVO. The SAPPHIRE study will assess whether using suprachoroidal CLS-TA in combination with intravitreal Eylea may offer an opportunity for earlier improved visual outcomes for RVO patients compared to Eylea monotherapy, and is also designed to evaluate required treatment frequency for the combination arm compared to the Eylea-alone control arm over the course of the trial.

"We expect to report topline 8-week primary endpoint data from the SAPPHIRE trial in the fourth quarter of 2018," said Daniel H. White, Chief Executive Officer and President of Clearside. "In the previously completed Phase 2 TANZANITE trial in RVO, suprachoroidal CLS-TA used with intravitreal Eylea showed the potential to provide better vision, faster onset of action and a longer duration of action than treatment with intravitreal Eylea alone. In TANZANITE, 61% of patients in the combination arm gained at least 15 ETDRS letters, or three lines of vision, at eight weeks, compared to 39% of patients in the control arm. Based on the observations from the TANZANITE trial, we believe the SAPPHIRE study has the potential to show that using suprachoroidal CLS-TA with an intravitreal anti-VEGF agent may offer an opportunity for both improved visual outcomes and a reduced treatment burden for RVO patients."

More details about Clearside's RVO clinical development program are available via the company's current corporate presentation, which can be accessed at http://ir.clearsidebio.com/events-and-presentations.

About Suprachoroidal CLS-TA

Suprachoroidal CLS-TA, Clearside's first investigational treatment, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye via the suprachoroidal space, or SCS™, which is the space located between the choroid and the outer protective layer of the eye known as the sclera. CLS-TA has been observed to reduce inflammation and other complications that lead to swelling of the macula, a leading cause of visual impairment and blindness. Clearside's proprietary suprachoroidal treatment approach is designed to enable rapid dispersion of a high amount of medicine to the back of the eye so that adequate medicine reaches and stays at the site of disease and has potential to act longer. This approach has potential to provide efficacy advantages and require fewer treatments and office visits while minimizing harm to the surrounding healthy parts of the eye.

Suprachoroidal CLS-TA, used either alone or together with an intravitreal anti-VEGF agent, is being studied as part of Clearside's pipeline of treatments for unmet or underserved sight-threatening eye diseases that manifest in the retina and the choroid.

About Retinal Vein Occlusion and the SAPPHIRE Trial

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.

As RVO is one of the most aggressive retinal vascular diseases that can lead to vision impairment and potential permanent vision loss, there is a strong need to develop new treatment approaches that are both effective and more durable than currently approved therapies.

SAPPHIRE is a multicenter, multi-country, randomized, masked, controlled Phase 3 clinical trial of suprachoroidal CLS-TA used in combination with intravitreally administered Eylea for the treatment of RVO. Patients randomized into the combination arm will receive suprachoroidal CLS-TA together with intravitreal Eylea at the beginning of the trial, intravitreal Eylea alone at week 4, and suprachoroidal CLS-TA together with intravitreal Eylea at weeks 12 and 24. Patients randomized into 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. The primary endpoint of this trial is the proportion of patients in the combination treatment arm, compared to the intravitreal Eylea-alone control arm, with improvements in best corrected visual acuity from baseline of at least 15 letters on the Early Treatment Diabetic Retinopathy Study ("ETDRS") scale at eight weeks after initial treatment. Safety and efficacy analyses will also be conducted at the 24-week visit and at an end of year study exit visit.

About Clearside

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases. Clearside's proprietary suprachoroidal treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. The company's unique platform for eye disease treatments is inherently flexible and intended to work with established medicines, new formulations of medicines, as well as future innovations. Clearside's pipeline includes advanced and pre-clinical product candidates in diseases where macular edema is a common complication, including uveitis, RVO and diabetic macular edema ("DME"). Clearside's

most advanced program is in non-infectious uveitis and it expects to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for use of suprachoroidal CLS-TA for the treatment of macular edema associated with non-infectious uveitis by the end of 2018. The company is also conducting two ongoing Phase 3 trials of suprachoroidal CLS-TA with an intravitreal anti-VEGF agent in patients with RVO. In addition, Clearside recently announced positive topline results from a Phase 2 clinical trial of suprachoroidal CLS-TA used with Eylea in patients with DME, and is continuing to analyze additional data from the trial as it becomes available. Clearside is headquartered in Alpharetta, GA. For more information, please visit http://www.clearsidebio.com. Follow @clearsidebio on Twitter and Linkedin.

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, including the timing of topline data from the SAPPHIRE trial, the potential attributes and benefits of Clearside's product candidates, and the timing of a potential submission of an NDA with the FDA. 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, 2017, filed with the U.S. Securities and Exchange Commission ("SEC") on March 16, 2018, and Clearside's other periodic and current reports filed with the SEC from time to time. 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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