Clearside Biomedical Provides Update on Two Phase 3 Clinical Trials of CLS-TA in Retinal Vein Occlusion

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ALPHARETTA, Ga., March 06, 2018 (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 ("TOPAZ") of suprachoroidal CLS-TA used with an intravitreally administered anti-VEGF agent ("intravitreal anti-VEGF agent") for the treatment of macular edema associated with Retinal Vein Occlusion ("RVO").

Suprachoroidal CLS-TA is Clearside's 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.

TOPAZ is a multicenter, randomized, masked, controlled trial to assess the safety and efficacy of suprachoroidal CLS-TA used together with one of two intravitreal anti-VEGF agents, Lucentis® (ranibizumab) or Avastin® (bevacizumab) in treatment naïve patients with RVO. Patients in the combination arm of the trial will receive suprachoroidal CLS-TA together with an intravitreal anti-VEGF agent at the beginning of the trial, an intravitreal anti-VEGF agent alone at week 4, and suprachoroidal CLS-TA together with an intravitreal anti-VEGF agent at weeks 12 and 24. Patients in the control arm will receive an intravitreal anti-VEGF agent alone at the beginning of the trial and every four weeks thereafter through week 24. After 24 weeks, patients in both arms 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. Several secondary efficacy and safety endpoints will also be evaluated. Clearside anticipates total enrollment of approximately 460 patients in this Phase 3 trial.

"TOPAZ is our second Phase 3 trial of suprachoroidal CLS-TA with an intravitreal anti-VEGF agent in patients with RVO," said Daniel H. White, Chief Executive Officer and President of Clearside. "Our first Phase 3 RVO study, called SAPPHIRE, is evaluating suprachoroidal CLS-TA in combination with intravitreal Eylea. Accordingly, if the primary endpoints are met in both the TOPAZ and SAPPHIRE trials, we expect to seek an agnostic label in the United States, where suprachoroidal CLS-TA can be used together with any anti-VEGF agent for the treatment of RVO."

Clearside also announced today that, based on patient enrollment progress, it now expects to report preliminary data from the SAPPHIRE trial in the fourth quarter of 2018 instead of the first quarter of 2019.

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 blinding eye diseases where the pathologies manifest in the retina and the choroid.

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 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 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, where macular edema is a common complication.

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 preliminary data from the SAPPHIRE trial, 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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