Clearside Biomedical Announces SAPPHIRE Phase 3 Study of Combination Therapy in Retinal Vein Occlusion Did Not Meet Its Primary Endpoint

November 5, 2018

- Focusing Resources on Uveitis Program; NDA Filing Expected Fourth Quarter 2018 -

- Company to Host Conference Call at 8:30 a.m. ET to Review the 8-Week Topline Data -

ALPHARETTA, Ga., Nov. 05, 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 that the primary endpoint was not achieved in its Phase 3 clinical trial ("SAPPHIRE") investigating the superiority of XIPERE (formerly "suprachoroidal CLS-TA") used together with the intravitreal anti-VEGF agent EYLEA® (aflibercept) ("intravitreal Eylea"), compared to intravitreal Eylea monotherapy, for the treatment of retinal vein occlusion ("RVO"). The primary endpoint of this trial was the proportion of patients in the combination treatment arm, compared to the intravitreal Eylea-alone control arm, with improvements in best corrected visual acuity ("BCVA") from baseline of at least 15 letters on the Early Treatment Diabetic Retinopathy Study ("ETDRS") scale at eight weeks after initial treatment.

"In the SAPPHIRE trial, approximately 50% of patients in both arms showed at least a 15 letter improvement in vision; unfortunately, there was no additional benefit for patients receiving XIPERE together with intravitreal Eylea," said Daniel White, Chief Executive Officer and President of Clearside. "In light of these 8-week topline data, we plan to discontinue clinical development of combination therapy for RVO, which includes SAPPHIRE and its companion Phase 3 clinical trial, TOPAZ."

"We believe the opportunity in our primary indication, uveitis, remains very attractive. Awareness and acceptance of the strong clinical profile of XIPERE as a potential monotherapy in treating uveitic macular edema is growing, and we remain on track to submit our NDA for this indication before the end of this year," added Mr. White.

Topline SAPPHIRE Trial Results

SAPPHIRE, a multicenter, multi-country, randomized, masked, controlled Phase 3 clinical trial, enrolled 460 patients with treatment naïve RVO. A similar proportion of patients in both arms of the SAPPHIRE trial gained at least 15 ETDRS letters in BCVA at eight weeks, showing no additional visual outcome benefit for patients in the XIPERE-plus- intravitreal Eylea combination arm compared to patients in the intravitreal Eylea-alone control arm. The safety profile appeared consistent with previous studies of XIPERE through 8 weeks.

Conference Call & Webcast Details

Clearside invites all interested parties to participate in a conference call today at 8:30 a.m. Eastern Time, during which management will discuss the 8-week topline data from the SAPPHIRE trial. To participate in this conference call, please dial (844) 263-8310 (U.S.) or (213) 358-0959 (international), conference ID 1699836, approximately 10 minutes prior to the start time. A live, listen-only audio webcast of the conference call can be accessed by visiting the "Investor Relations" section at www.clearsidebio.com. An archive of the webcast will be available until February 5, 2019.

About XIPERE

XIPERE, 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. Clearside's proprietary suprachoroidal treatment approach is designed to enable rapid dispersion 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.

XIPERE 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 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 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 XIPERE for the treatment of uveitic macular edema by the end of 2018. In addition, Clearside recently announced positive topline results from a Phase 2 clinical trial of XIPERE used with Eylea in patients with DME, and is continuing to analyze additional data from the trial. 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, 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 SEC on March 16, 2018, 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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