Clearside Biomedical's TANZANITE Extension Study in Patients with Macular Edema Associated with Retinal Vein Occlusion Presented at the 40th Annual Macula Society Meeting

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74% of RVO Patients Receiving CLS-TA for Suprachoroidal Administration Together with Intravitreally Administered EYLEA® Did Not Receive Any Additional Treatment Over 9 Months

ALPHARETTA, Ga., June 08, 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, announced that, today at the 40th Annual Macula Society Meeting in Singapore, Charles C. Wykoff , MD, PhD, presented preliminary results from a non-interventional and retrospective trial (the "Extension Study") of patients who had participated in the completed Phase 2 trial of CLS-TA for suprachoroidal administration ("suprachoroidal CLS-TA"), Clearside's proprietary suspension formulation of the corticosteroid triamcinolone acetonide, used together with intravitreally administered EYLEA® (aflibercept) ("intravitreal Eylea") for the treatment of macular edema associated with retinal vein occlusion ("RVO").

There were a total of 46 treatment-naïve patients with RVO who were enrolled in the Phase 2 trial, known as TANZANITE. The trial included both an active arm of patients who received concomitant suprachoroidal CLS-TA and intravitreal Eylea (the "combination arm") and a control arm of patients receiving only intravitreal Eylea (the "Eylea arm"). As previously reported, patients in the combination arm achieved both additional visual acuity improvements and macular edema reductions over a 3-month period following initial dosing, as compared to patients in the control arm.

"Based on the fact that so few patients in the TANZANITE combination arm received retreatment, and cognizant of the substantial unmet need associated with frequent office visits and injections required in this patient population, our team conducted an extended evaluation to better assess the duration of effect of the combination treatment and the potential to reduce the burden of therapy," commented Daniel H. White, Clearside's Chief Executive Officer and President.

The objective of the Extension Study was to assess the durability of suprachoroidal CLS-TA in combination with intravitreal Eylea for an additional 6 months following completion of the TANZANITE trial. RVO patients who participated in the TANZANITE trial and did not receive any additional Eylea treatment during its 3-month evaluation period were eligible to be included in the Extension Study. Of the 32 eligible patients, the medical records of 31 patients were obtained for review. Using data from the TANZANITE trial and the Extension Study, time to first RVO re-treatment following the baseline dosing in TANZANITE was determined for patients in both arms. In the preliminary analysis presented today by Dr. Wykoff, 17 of the 23 patients in the combination arm of the TANZANITE trial, or 74%, did not receive any additional treatment over the 9-month period, compared to only 4 of 23 patients, or 17%, in the Eylea arm.

Dr. Wykoff commented, "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. While further study is needed, the data from the TANZANITE trial and the Extension Study imply that suprachoroidal CLS-TA in combination with intravitreal Eylea may result in improvements in vision seen as early as month 1 and maintained through month 3, as well as a substantial prolongation of treatment interval. Further research is needed to fully establish the potential clinical benefit of this therapeutic approach. To that end, Clearside launched the first of two planned Phase 3 RVO clinical trials, known as SAPPHIRE, in the first quarter of 2017."

"We are encouraged by these data, which suggest that suprachoroidal CLS-TA in combination with intravitreal Eylea for the treatment of RVO in treatment-naïve patients has the potential to not only provide better vision and a faster onset of action, but also, based on the extension study, to lower the need for retreatment when compared to intravitreal Eylea monotherapy," said Mr. White.

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, RVO, diabetic macular edema and wet age-related macular degeneration. CLS-TA for suprachoroidal administration, used either alone or together with an intravitreal anti-VEGF agent, is part of Clearside's pipeline for the treatments of unmet or underserved blinding eye diseases where the pathologies manifest in the choroid and retina. 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 and the availability of data from Clearside's clinical trials. 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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