Clearside Biomedical Announces Positive Topline Results from Phase 2 Clinical Trial of CLS-TA Used with Eylea in Patients with Diabetic Macular Edema

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- *Primary and Secondary Endpoints Met in 6-month Trial*
- *Patients Treated with CLS-TA Achieved Comparable Vision Improvement With Fewer Treatments*

ALPHARETTA, Ga., May 31, 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 positive topline results from its Phase 2 clinical trial ("TYBEE") evaluating suprachoroidal CLS-TA used with intravitreally administered EYLEA ® (aflibercept) ("intravitreal Eylea") in patients with diabetic macular edema ("DME") over a 6-month evaluation period.

TYBEE, a multicenter, randomized, masked, controlled Phase 2 trial, enrolled 71 patients who were naïve to treatment for DME. Patients were randomized 1:1 to receive either quarterly treatments of suprachoroidal CLS-TA together with intravitreal Eylea (months 0 and 3) (the "combination arm") or four monthly treatments of intravitreal Eylea plus a sham suprachoroidal procedure (months 0, 1, 2 and 3) (the "control arm"), with patients in either arm receiving intravitreal Eylea treatment at months 4 and 5 as needed.

The trial met its primary endpoint of mean improvement in best corrected visual acuity ("BCVA") from baseline over six months as measured using the Early Treatment of Diabetic Retinopathy Trial ("ETDRS") scale. Patients in the combination arm gained an average of 12.3 ETDRS letters compared to 13.5 ETDRS letters in the Elyea alone control arm (p = 0.664).

"We are pleased with the topline results of this Phase 2 trial, which signals the potential utility of suprachoroidal CLS-TA to improve on the existing standard of care in DME, another sight-threatening disease like RVO and uveitis," said Daniel White, Clearside's Chief Executive Officer and President. "Based on the TYBEE data, we believe suprachoroidal CLS-TA, when given together with an anti-VEGF agent, has potential to provide a more lasting response to treatment, thereby substantially lowering the treatment frequency and burden for DME patients."

Additionally, administration of suprachoroidal CLS-TA together with intravitreal Eylea met a key secondary endpoint with a mean reduction from baseline of 208 microns in central subfield thickness ("CST") of the retina at six months, compared to a 177 micron mean reduction in the control arm (p = 0.156). Further, 93% of patients in the combination arm had a greater than 50% reduction in excess CST at six months, compared to 73% of patients in the control arm.

Suprachoroidal CLS-TA used together with intravitreal Eylea was generally well tolerated, with no treatment-related serious adverse events reported in the TYBEE trial through the 24 week evaluation period. Elevated intraocular pressure adverse events were reported for 8.3% of patients in the combination arm, compared to 2.9% of patients in the control arm. Both the combination and control arms reported cataract adverse events, with approximately 5.6% of patients in the combination arm and 2.9% of patients in the control arm developing cataracts.

Clearside is continuing to analyze data from the TYBEE trial and detailed results will be shared at an upcoming medical meeting.

"These data add to the growing body of evidence that the combination approach with suprachoroidal CLS-TA has potential to provide a clinically meaningful improvement in vision with fewer treatments in DME," said Glenn Noronha, PhD., Clearside's Chief Scientific Officer. Based on the initial results from this trial, we will begin evaluating a Phase 3 program to continue investigating the potential for Clearside's proprietary treatment approach in patients with diabetic eye disease."

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 specifically reduces 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 DME

DME is the most common cause of vision loss in people with diabetes mellitus. A consequence of diabetic retinopathy, DME is swelling of the retina caused by leaking blood vessels. DME affects up to 30% of people who have had diabetes for 20 years or more, and if untreated, approximately 20 to 30% of people who have it will experience moderate visual loss.

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, retinal vein occlusion, DME and wet age-related macular degeneration. Clearside's most advanced program is in non-infectious uveitis and it expects to file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for use of suprachoroidal CLS-TA in non-infectious uveitis by the end of 2018. 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 potential clinical development of Clearside's product candidates, the potential attributes and benefits of Clearside's product candidates, the availability of detailed results from the TYBEE trial, the timing of a potential Phase 3 program in DME, 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 reports filed from time to time 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.

Contacts:

Stephen Kilmer
Investor Relations
(678) 270-3631
stephen.kilmer@clearsidebio.com

Charles Deignan
Chief Financial Officer
(678) 270-4005
charlie.deignan@clearsidebio.com

Primary Logo

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