Clearside Biomedical Receives Notification of FDA Acceptance of NDA Filing for XIPERE™ (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection with PDUFA Date Set for October 19, 2019

February 20, 2019

ALPHARETTA, Ga., Feb. 20, 2019 (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, announced today that it received notification from the U.S. Food and Drug Administration (FDA) that the Agency has accepted for review the New Drug Application (NDA) for XIPERE (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection for the treatment of macular edema associated with uveitis. The FDA has determined that the application is sufficiently complete to permit a substantive review.

The PDUFA (Prescription Drug User Fee Act) goal date has been assigned for October 19, 2019. This date reflects a standard review period and is consistent with management's expectations for the 505(b)(2) filing.

"We are delighted with this positive news on our XIPERE NDA. If XIPERE is approved, Clearside will have the first therapy indicated for patients suffering from macular edema associated with uveitis," said Daniel H. White, President and Chief Executive Officer. "Macular edema is the leading cause of vision loss, and even blindness, in uveitis patients, and we are now one step closer to treating this underserved patient population. Over the last several months, our team has worked diligently to reach this milestone and we are now preparing to launch the product if approved."

The NDA filing is supported by data from the Phase 3, PEACHTREE clinical trial that demonstrated significant and clinically meaningful improvement in vision for patients with macular edema associated with non-infectious uveitis, and that improvement was achieved across all anatomical locations of uveitis. Also, in patients with active inflammation at baseline, resolution was achieved in more than two-thirds of those treated with XIPERE across three commonly used measures of inflammation: vitreous haze, anterior chamber cells and anterior chamber flare.

About PEACHTREE

PEACHTREE, a randomized, masked, sham-controlled Phase 3 trial, enrolled 160 patients with macular edema associated with non-infectious uveitis, and compared XIPERE dosed every 12 weeks to sham control. The PEACHTREE trial met its primary endpoint, with 47% of patients in the XIPERE arm gaining at least 15 letters in best corrected visual acuity from baseline at week 24, compared to 16% of patients in the sham control arm ($p<0.001$), using standardized Early Treatment of Diabetic Retinopathy Study (ETDRS) visual acuity testing. All key secondary and additional endpoints of the PEACHTREE trial were also achieved.

About Uveitis and Macular Edema

Uveitis is a set of ocular inflammatory conditions and is one of the leading causes of vision loss, affecting approximately 350,000 patients in the United States and more than one million worldwide. Approximately one-third of these patients develop uveitic macular edema, a build-up of fluid in the macula, the area of the retina responsible for sharp, straight-ahead vision. Macular edema is the leading cause of vision loss and blindness in uveitis patients and can occur from uveitis affecting any anatomic location - anterior, intermediate, posterior or pan. The uveitis market is expected to grow by 2024 to nearly $550 million in the United States and over $1 billion globally.

About XIPERE

XIPERE (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye via suprachoroidal injection for the treatment of macular edema associated with uveitis. Clearside's patented technology is designed to deliver drug to the suprachoroidal space located between the choroid and the outer protective layer of the eye, known as the sclera. Suprachoroidal injection enables the rapid and adequate dispersion of medicine to the back of the eye, offering the potential for the medicine to act longer and minimize harm to the surrounding healthy parts of the eye, thus potentially providing advantageous and sustained efficacy with a favorable safety profile.

About Clearside Biomedical

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 such as gene therapy. Clearside is headquartered in Alpharetta, GA. For more information, please visit http://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 Clearside's product candidates, the potential attributes and benefits of Clearside's product candidates, and the potential approval and commercialization of XIPERE in the United States. 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, Clearside's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 8, 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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