Presentation of Clearside Biomedical's Extension Study of PEACHTREE for XIPERE™ Exhibits Durability Following Second Dose

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ALPHARETTA, Ga., Jan. 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 data from MAGNOLIA, an extension study of PEACHTREE, its pivotal Phase 3 trial of XIPERE™ (formerly "suprachoroidal CLS-TA") in patients with macular edema associated with non-infectious uveitis, was presented by Pauline Merrill, MD during the winter symposium of the American Uveitis Society in Park City, UT. Dr. Merrill is a Partner at Illinois Retina Associates and Section Director of Uveitis in the Department of Ophthalmology at Rush University Medical Center.

Dr. Merrill's shared the extension study results in a presentation entitled "Suprachoroidal CLS-TA Maintains Efficacy Outcomes Through 48-weeks in Uveitic Macular Edema subjects: Results of the MAGNOLIA Phase 3 Extension Study." MAGNOLIA followed 28 of the 96 patients who were in the XIPERE treatment arm of PEACHTREE, across 22 of the clinical sites utilized in PEACHTREE, for six additional months without treatment to better understand XIPERE's long-term clinical profile.

"In MAGNOLIA, 50% of XIPERE-treated subjects maintained efficacy through 36 additional weeks after their second suprachoroidal injection of XIPERE, without requiring additional treatment," stated Dr. Merrill. "These data are important to clinicians as we seek new options to reduce the treatment burden on our patients while maintaining the vision gains offered by the treatment, as seen in the PEACHTREE trial."

"In December, we submitted a new drug application to the FDA for XIPERE to treat macular edema associated with uveitis," said Clearside's Chief Medical Officer, Tom Ciulla, MD. "The data from MAGNOLIA expands our understanding of XIPERE and continues to increase our confidence that, if approved, can become an important new treatment option for uveitic macular edema patients. We are actively preparing to introduce XIPERE to the market, should the FDA provide an approval."

The most common adverse events seen in the MAGNOLIA trial included cataracts and increases in intraocular pressure and were consistent with previous trials of XIPERE. No serious adverse events were reported.

About MAGNOLIA

MAGNOLIA was a non-interventional, prospective observational extension study of the Phase 3 PEACHTREE study, designed to characterize the clinical profile of XIPERE through 48-weeks. In MAGNOLIA, 28 subjects who were treated with XIPERE at baseline and week 12 and followed through week 24 in the PEACHTREE study were followed for an additional 24 weeks. The mean time to rescue therapy in this subset of patients was over 9 months from their second injection in the PEACHTREE study. No serious adverse events related to study treatment were observed.

About XIPERE

XIPERE, Clearside's first investigational treatment to reach New Drug Application ("NDA") submission to the U.S. Food and Drug Administration ("FDA"), is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye via suprachoroidal injection into 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 the potential to act longer, while minimizing harm to the surrounding healthy parts of the eye. This approach has potential to provide efficacy advantages and improved durability.

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, as measured using the Early Treatment of Diabetic Retinopathy Study scale, from baseline at week 24, compared to 16% of patients in the sham control arm ($p<0.001$). All key secondary and additional endpoints of the PEACHTREE trial were also achieved.

About Uveitis

Uveitis, a set of inflammatory conditions affecting the eye, is one the world's leading causes of blindness. Uveitis occurs in about 350,000 patients in the United States and is typically found in both eyes. The uveitis market is expected to grow by 2024 to nearly $550 million in the United States and over $1 billion globally. Macular edema is the build-up of fluid in the macula, an area in the center of the retina responsible for sharp, straight-ahead vision. Fluid buildup causes the macula to swell and thicken, which distorts vision. Macular edema occurs in approximately one-third of all non-infectious uveitis cases and is the leading cause of vision impairment and vision loss in these patients.

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. 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 potential 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 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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