Clearside Biomedical Submits New Drug Application for XIPERE™ for the Treatment of Macular Edema Associated with Uveitis

December 19, 2018

ALPHARETTA, Ga., Dec. 19, 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 it has submitted a New Drug Application ("NDA") for XIPERE ™ to the U.S. Food and Drug Administration ("FDA") for the treatment of macular edema associated with uveitis.

The uveitis market is expected to grow by 2024 to nearly $550 million in the United States and over $1 billion globally. Uveitis is a set of ocular inflammatory conditions and is one of the leading causes of vision loss worldwide, 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.

If approved by the FDA, XIPERE would be the first therapy for macular edema associated with uveitis.

"Based on the data from PEACHTREE, our pivotal Phase 3 clinical trial, we believe that XIPERE has the potential to become a new paradigm in the treatment of uveitic macular edema," said Daniel White, Chief Executive Officer and President of Clearside. "PEACHTREE was the first clinical trial to demonstrate significant improvement in vision for patients with macular edema associated with non-infectious uveitis, and that improvement was achieved across all anatomical locations of uveitis. In addition, signs of inflammation resolved in more than two-thirds of patients treated with XIPERE across three commonly used measures of inflammation in the eye: vitreous haze; anterior chamber cells and anterior chamber flare. We have an experienced commercial team preparing for the potential launch of XIPERE and we also plan to submit applications for regulatory approval in select markets outside of the U.S."

About XIPERE

XIPERE, Clearside's first investigational treatment to reach NDA submission, 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 require fewer treatments.

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 ($p<.001$). All key secondary and additional endpoints of the PEACHTREE trial were also achieved.

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 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 potential clinical development of Clearside's product candidates, the availability of data from Clearside's clinical trials, the timing of marketing authorization applications with regulatory agencies in Europe and other jurisdictions, and the potential commercialization of XIPERE, both in the United States and internationally. 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, 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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