Clearside Biomedical Announces Resubmission of New Drug Application for XIPERE™ for Treatment of Macular Edema Associated with Uveitis

May 3, 2021

ALPHARETTA, Ga., May 03, 2021 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (Nasdaq: CLSD), a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases, announced today the resubmission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) for the treatment of macular edema associated with uveitis.

Clearside's resubmission is a full and complete response to all of the items identified in the Complete Response Letter (CRL) received from the FDA on October 18, 2019. Clearside believes this application will be considered a Class 2 resubmission, with a targeted six-month review timeline under the Prescription Drug User Fee Act.

"The resubmission of the XIPERE NDA is an important milestone for Clearside," said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer of Clearside Biomedical. "As the pioneers in treating back of the eye diseases through the suprachoroidal space, we believe our extensive clinical experience with XIPERE shows the potential for a reliable, non-surgical, office-based method for the treatment of a broad range of retinal diseases. We appreciate the continued support and input from our global commercialization partners, Bausch + Lomb and Arctic Vision, as we look towards the opportunity to improve the lives of patients suffering from macular edema associated with uveitis."

About XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension)

XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye 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 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. Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc. (NYSE/TSX: BHC), has the exclusive license for the commercialization and development of XIPERE in the United States and Canada and an exclusive option for commercialization and development of XIPERE in Europe and the United Kingdom, Australia and New Zealand, and/or South America and Mexico. Arctic Vision, a specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE in Greater China and South Korea. XIPERE is not yet approved in any jurisdiction.

About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing and delivering treatments that restore and preserve vision for people with serious back of the eye diseases. Clearside's proprietary SCS Microinjector ® targets the suprachoroidal space (SCS®) and offers unique access to the macula, retina and choroid where sight-threatening disease often occurs. The Company's SCS injection platform is an inherently flexible, in-office, non-surgical procedure, intended to provide targeted delivery to the site of disease and to work with both established and new formulations of medications. For more information, please visit 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 statements regarding the clinical development of XIPERE, including whether FDA will accept, and the timing of potential FDA approval of, the NDA resubmission. 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, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in Clearside's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2021, 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.

Investor and Media Contacts:

Jenny Kobin
Remy Bernarda
ir@clearsidebio.com
(678) 430-8206

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