Clearside Biomedical's Partner Arctic Vision Reports Positive Topline Results from Phase 3 Clinical Trial of ARCATUS® for Suprachoroidal Use in Uveitic Macular Edema Patients in China

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Primary and Secondary Endpoints Achieved with Favorable Tolerability and Safety Profile

ALPHARETTA, Ga., July 29, 2024 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (Nasdaq: CLSD), a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®), announced that its partner, Arctic Vision, reported positive topline results from its Phase 3 clinical trial of ARCATUS® (ARVN001) for the treatment of Uveitic Macular Edema (UME) in China. In addition, Arctic Vision announced that new drug applications (NDAs) for ARCATUS have been officially accepted in Australia and Singapore.

ARCATUS is Arctic Vision's name for XIPERE ® (triamcinolone acetonide injectable suspension) for suprachoroidal use which was originally developed by Clearside. Arctic Vision is a specialty ophthalmology company based in China that has the exclusive license for the commercialization and development of XIPERE® in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries.

"This new, positive Phase 3 data from Arctic Vision reinforces the global product opportunity of XIPERE as a key treatment option for patients with uveitic macular edema," said, George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer. "XIPERE was our first FDA-approved product and has led the way for our proprietary suprachoroidal space (SCS®) injection treatment approach that offers unprecedented access to the back of the eye, where sight-threatening disease occurs. Our partner, Arctic Vision, is making excellent progress in bringing this important therapy to market in the Asia-Pacific region."

Arctic Vision announced the following results from its Phase 3 trial. The trial met the primary endpoint and secondary endpoints and demonstrated significantly better visual acuity improvement and edema control in the treatment arm over the sham arm. In the study, 38.5% of ARVN001-treated patients gained 15 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or more in vision vs 9.4% in the sham group. Central subfield thickness (CST) reduction was 204.3 microns in ARVN001-treated patients vs 1.6 microns in the sham group at week 24. Both reached statistical significance ($p<0.001$). Furthermore, the mean best corrected visual acuity (BCVA) gain was 9.6 letters at week 4 and 12.2 letters at week 24. Similarly, the CST changes achieved over 200 microns reduction at week 4 and maintained the reduction to week 24. There were no ocular serious adverse events (SAEs) or new safety signals reported. A link to the Arctic Vision press release is available here.

About XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use

XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use is a proprietary suspension of the corticosteroid triamcinolone acetonide for administration to the suprachoroidal space for the treatment of macular edema associated with uveitis. Bausch + Lomb, a leading global eye health company dedicated to helping people see better to live better, has the exclusive license for the commercialization and development of XIPERE in the United States and Canada. Arctic Vision, a specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE, which they refer to as ARCATUS®, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. XIPERE was approved by the U.S. Food and Drug Administration in October 2021 and is commercially available in the U.S. A link to the full prescribing information is available at https://www.xipere.com/hcp/#isi.

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 Clearside Biomedical, Inc.

Clearside Biomedical, Inc. is a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®). Clearside's SCS injection platform, utilizing the Company's patented SCS Microinjector ®, enables an in-office, repeatable, non-surgical procedure for the targeted and compartmentalized delivery of a wide variety of therapies to the macula, retina, or choroid to potentially preserve and improve vision in patients with sight-threatening eye diseases. Clearside is developing its own pipeline of small molecule product candidates for administration via its SCS Microinjector. The Company's lead program, CLS-AX (axitinib injectable suspension), for the treatment of neovascular age-related macular degeneration (wet AMD), is in Phase 2b clinical testing. Clearside developed and gained approval for its first product, XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, which is available in the U.S. through a commercial partner. Clearside also strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. For more information, please visit clearsidebio.com and follow us on LinkedIn and X.

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 potential benefits of XIPERE and Clearside’s suprachoroidal delivery technology. 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, 2023, filed with the U.S. Securities and Exchange Commission (SEC) on March 12, 2024 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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