Clearside Biomedical's Asia-Pacific Partner, Arctic Vision, Announced Acceptance of its New Drug Application for ARCATUS® for Regulatory Review in China for the Treatment of Uveitic Macular Edema

February 20, 2025

ALPHARETTA, Ga., Feb. 20, 2025 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (Nasdaq: CLSD) ("Clearside" or the "Company"), a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®), reported that Arctic Vision's New Drug Application (NDA) for ARCATUS ® for the treatment of uveitic macular edema (UME) has been formally accepted for review by the Center for Drug Evaluation of China National Medical Products Administration. The NDA submission is supported by positive topline results from Arctic Vision's Phase 3 UME clinical trial in China.

ARCATUS (known as XIPERE® in the U.S.) utilizes Clearside's proprietary SCS Microinjector ® and is the first and currently only approved suprachoroidal therapy to treat UME. It has already been approved by the Food and Drug Administration in the United States, Therapeutic Goods Administration in Australia, and the Health Sciences Authority in Singapore.

George Lasezkay, PharmD, JD, President and Chief Executive Officer of Clearside, commented, "Our partner, Arctic Vision, continues to make excellent progress in advancing our product in the Asia-Pacific region. The Chinese UME market is large, with several million uveitis patients[1]. As the first SCS® injection therapy, our product utilizes an innovative delivery platform that 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."

Arctic Vision is a China-based ophthalmic biotech company that has the exclusive license for the commercialization and development of XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, which they refer to as ARCATUS® or ARVN001, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. Arctic Vision has a commercial collaboration agreement with Santen Pharmaceutical Co., Ltd. to commercialize ARVN001 for the treatment of UME and certain other ophthalmic indications under development in China, excluding Taiwan, Hong Kong and Macau. In addition, Arctic Vision is developing ARVN001 for other ocular retinal diseases, including diabetic macular edema.

About Clearside's Suprachoroidal Space (SCS ®) Injection Platform and SCS Microinjector®

Clearside's patent protected, proprietary suprachoroidal space (SCS ®) injection treatment approach offers unprecedented access to the back of the eye, where sight-threatening disease often occurs. The Company's unique platform is inherently flexible and intended to work with established and new formulations of medications. Clearside's patented SCS Microinjector ® can deliver a wide variety of drug candidates into the suprachoroidal space, providing targeted delivery to potentially improve efficacy and compartmentalization of medication to reduce or eliminate toxic effects on non-diseased cells. The SCS Microinjector is comprised of a syringe with a custom-designed hub and two 30-gauge hollow microneedles of varying lengths, each approximately one millimeter, optimizing insertion and suprachoroidal administration of drugs.

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. XIPERE is approved by the U.S. Food and Drug Administration and is commercially available in the United States. 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 U.S. and Canada. Arctic Vision, a China-based ophthalmic biotech company, has the exclusive license for the commercialization and development of XIPERE, which they refer to as ARCATUS® or ARVN001, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries.

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 global uveitis treatment market is projected to grow from approximately $2.3 billion in 2023 to $4.5 billion by 2032.[2]

Sources:

[1]Yang Peizeng, Liu Yizhi. Ophthalmology[M]. Beijing People's Medical Publishing House, 2017:238-264.

[2]Gotadki, Rahul, Market Research Future, Uveitis Treatment Market Research Report by Treatment Type, January 2025.

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®) to improve patient outcomes. 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), recently completed a Phase 2b clinical trial, and planning for a Phase 3 program is underway. 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 or 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®, Clearside’s suprachoroidal delivery technology and Clearside’s SCS Microinjector ®, as well as the growth of the uveitis treatment market. 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, Clearside’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on November 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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