Clearside Biomedical Partner Arctic Vision Executes Commercial Collaboration Agreement with Santen Pharmaceutical Co., Ltd for ARVN001 Suprachoroidal Space Injection Therapy for the Treatment of Uveitic Macular Edema

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- Partnership Creates New Opportunities to Address Unmet Needs Related to Posterior Segment Eye Diseases in China -

- Agreement Provides Additional Validation for Clearside's Suprachoroidal Space (SCS ®) Delivery Platform -

ALPHARETTA, Ga., Nov. 07, 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 today that the Company's Asia-Pacific partner, Arctic Vision, has signed a new commercial collaboration agreement with Santen Pharmaceutical Co., Ltd. for ARVN001, branded in the U.S. as XIPERE®, for the treatment of uveitic macular edema (UME) and certain other ophthalmic indications under development. Under the terms and conditions of the agreement, Arctic Vision has granted the rights of ARVN001 to Santen to commercialize the product candidate in China excluding Taiwan, Hong Kong and Macau. XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use was developed by Clearside and is currently being sold in the United States by Bausch + Lomb.

"This commercialization agreement provides additional strategic validation of our suprachoroidal delivery platform by another global pharmaceutical company," said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer of Clearside. "Our innovative drug delivery platform is now being used in commercial products and promising clinical development programs by Santen, Bausch + Lomb, AbbVie Inc., REGENXBIO Inc., Aura Biosciences, Inc. and BioCryst Pharmaceuticals, Inc."

"Arctic Vision has made excellent progress advancing our product in the Asia-Pacific region with a positive Phase 3 trial, regulatory review ongoing in Australia and Singapore, and a pending submission for approval in China. Leveraging the global capabilities of Santen to commercialize ARVN001, if approved in China, is another successful step to bring this important treatment to UME patients in the Asia-Pacific region. This partnership will enable training and use of our SCS Microinjector® in major international markets, which provides benefit to Clearside and all of our partners in driving the adoption of SCS delivery. Recently published data from a survey of U.S.-based retinal specialists indicated that the suprachoroidal injection technique was easy to learn and resulted in favorable patient outcomes consistent with clinical trial data," Dr. Lasezkay concluded.

Arctic Vision is a specialty ophthalmology company based in China that has the exclusive license for the commercialization and development of XIPERE, which they refer to as ARVN001, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. In July 2024, Arctic Vision announced positive topline results from its Phase 3 clinical trial in China in UME. They also have New Drug Applications for ARVN001 under review in Australia and Singapore for the treatment of UME. In addition, Arctic Vision is developing ARVN001 for other ocular retinal diseases including diabetic macular edema.

The joint press release issued by Arctic Vision and Santen can be accessed here.

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 system comprises a syringe, 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 specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE, which they refer to as ARVN001 or ARCATUS®, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. 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®) 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 Clearside's suprachoroidal delivery technology and Clearside's SCS Microinjector ®, and the potential approval and commercialization of ARVN001 in China. 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 June 30, 2024 filed with the SEC on August 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.

Source: Clearside Biomedical, Inc.

Investor and Media Contacts: Jenny Kobin Remy Bernarda ir@clearsidebio.com (678) 430-8206