Clearside Biomedical Expands XIPERE™ License Agreement with Arctic Vision to Include Australia, New Zealand, India and ASEAN Countries

September 9, 2021

– Increasing Global Awareness of Innovative Suprachoroidal Injection Platform –

ALPHARETTA, Ga., Sept. 09, 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 it has agreed to expand the territories covered by its exclusive license agreement with Arctic Vision, a China-based biotech company focused on innovative ophthalmic therapies. As now amended, the licensed territory for XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) has been expanded from Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea to also include Australia, New Zealand, India and the ASEAN Countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam).

"Over the past year, we have forged a strong relationship with Arctic Vision and have been impressed with their team's speed and dedication to bringing needed ophthalmic treatments to a large and important global region," said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer, Clearside Biomedical. "If approved, XIPERE will be the first therapy for macular edema associated with uveitis and will be the first approved therapeutic delivered into the suprachoroidal space. We are dedicated to providing global access to our clinically tested, non-surgical, repeatable micro-injection technology designed to unlock the potential clinical benefits of administering drugs into the suprachoroidal space."

XIPERE, referred to as ARVN001 by Arctic Vision, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the suprachoroidal space (SCS®) using Clearside's patented SCS Microinjector ®. The product candidate is being investigated for the treatment of macular edema associated with uveitis. In the U.S., Clearside's New Drug Application for XIPERE is under review by the U.S. Food and Drug Administration, with a Prescription Drug User Fee Act (PDUFA) action date of October 30, 2021. In China, Arctic Vision is planning to initiate a Phase 3 clinical trial of ARVN001 in the second half of 2021.

"We are very excited to expand the licensed territory of ARVN001 to two of the most important countries in the Pacific region," said Eddy (Hoi Ti) Wu, Ph.D., Founder and CEO of Arctic Vision. "Building our commercial reach into the overseas market has always been a major strategic goal, and this amendment greatly accelerates the process. Beginning with ARVN001, we strive to bring innovative eyecare solutions to the greater pan-Asia market."

Under the terms of the amended agreement, Clearside will receive a total of $3.0 million in upfront payments and is entitled to additional payments upon the achievement of certain regulatory and sales milestones in the newly added countries (including Australia, New Zealand, India and the ASEAN Countries). These financial terms for the new countries are in addition to the previously announced milestone payments for the achievement of specified events prior to and including receipt of approval of XIPERE in the United States and other development and ARVN001 approval and sales-based events in the original territory of Greater China and South Korea. Clearside is entitled to receive tiered royalties of 10% to 12% based on annual net sales of ARVN001 in all territories covered by the amended agreement.

Clearside is also partnered with an affiliate of Bausch Health, which holds the exclusive license for the commercialization and development of XIPERE in the United States and Canada. Clearside is currently in discussions with other potential partners regarding licensing the rights to commercialize and develop XIPERE in the European Union, the United Kingdom, South America and Mexico.

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 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 potential approval of XIPERE by the FDA, the commercial potential of XIPERE and Arctic Vision's clinical development of ARVN001 and potential launch in the licensed territories. 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.

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Source: Clearside Biomedical, Inc.