Clearside Biomedical Announces Option Exercise by REGENXBIO for Global License for Use of SCS Microinjector™ in AAV Gene Therapy Delivery

October 30, 2019

ALPHARETTA, Ga., Oct. 30, 2019 (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 that REGENXBIO Inc. (Nasdaq: RGNX) has exercised its option under the previously announced option and license agreement to license Clearside's proprietary, in-office SCS Microinjector™ for the delivery of adeno-associated virus (AAV)-based therapeutics, including but not limited to RGX-314 delivery to the suprachoroidal space to potentially treat wet age-related macular degeneration (wet AMD), diabetic retinopathy (DR), and other conditions for which chronic anti-vascular endothelial growth factor (anti-VEGF) treatment is currently the standard of care.

"Our recent partnerships with REGENXBIO, Bausch Health, and Aura Biosciences demonstrate the broad applicability of our suprachoroidal space injection platform to potentially treat multiple ocular diseases including wet AMD, uveitic macular edema, and choroidal melanoma. With these collaborations and planned internal research and development efforts, we look forward to continuing to expand our pipeline," said George Lasezkay, Pharm.D., J.D., Chief Executive Officer of Clearside.

"Results from multiple preclinical studies support the potential safety and effectiveness of suprachoroidally administered AAV-based gene therapy, and we are excited to advance our partnership with REGENXBIO," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer of Clearside. "Wet AMD and diabetic retinopathy are the two most common causes of irreversible blindness in the United States, and several large 'real world' studies reveal under-treatment and outcomes that fall short of those reported in clinical trials. Utilizing our SCS Microinjector, delivery of RGX-314 may provide patients with access to one-time gene therapy treatment in a range of patient care settings."

Under the terms of the option and license agreement, Clearside earned $2.0 million related to REGENXBIO's exercise of the option and signing of the original research agreement. Clearside is also eligible to receive up to $34 million in total development milestones across multiple indications, up to $102 million in sales milestones and mid-single digit royalties on net sales of products using the SCS Microinjector. REGENXBIO will be responsible for all development, regulatory and commercialization activities for their gene therapy product candidates. Clearside will be responsible for supplying the SCS Microinjector in support of REGENXBIO's preclinical studies, clinical studies and commercial use.

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™ targeting the suprachoroidal space (SCS) 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, as well as future therapeutic innovations such as gene therapy. 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 potential application of the SCS Microinjector for AAV gene therapy and the potential benefits of the SCS injection platform. 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, 2018, filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2019, Clearside's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 8, 2019, 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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