Clearside Biomedical's Suprachoroidal Space Injection Platform Featured at Multiple Ophthalmology and Gene Therapy Medical Meetings

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- SCS injection platform continues to be well-received by the medical community -

- Suprachoroidal administration may offer targeted delivery of gene therapies without risks of vitrectomy and subretinal surgery -

ALPHARETTA, Ga., May 01, 2019 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases, announced today that multiple presentations were made on Clearside's Suprachoroidal Space (SCS) injection platform at ophthalmology and gene therapy medical meetings in Vancouver, British Columbia. The presentations highlighted the potential benefits of Clearside's SCS injection platform when utilized in uveitis patients and with gene therapy.

"Our SCS injection platform continues to be well-received by the medical community," stated Thomas A. Ciulla, M.D., MBA, Clearside Chief Medical Officer. "We are excited about our October PDUFA (Prescription Drug User Fee Act) date for XIPERE™ (triamcinolone acetonide ophthalmic suspension), and our recent congress presentations have attracted great interest from uveitis and retinal specialists ahead of our anticipated launch. We are equally encouraged by the growing interest in our SCS injection platform as a potential method to deliver ocular gene therapy in an office setting. We plan to continue our work in this area in an effort to optimize the SCS procedure for gene therapy in these non-clinical models and identify the appropriate indications to potentially improve outcomes for patients."

Gene Therapy Presentations:

Summary: At the Association for Research in Vision and Ophthalmology (ARVO) 2019 Conference, multiple posters were presented utilizing a suprachoroidal approach to deliver gene therapies in non-clinical models. In totality, the data presented at the conference suggests that suprachoroidal administration has the potential to offer targeted delivery of gene therapies without risks of vitrectomy and subretinal surgery. These projects provide valuable insight to Clearside as the company looks to optimize the procedure for gene therapy delivery and design a path forward for its proprietary SCS injection platform in this setting.

Glenn Chung-Wing Yiu, M.D., Ph.D., Assistant Professor of Ophthalmology, UC Davis, presented a poster entitled, "*Suprachoroidal injection of AAV8 for ocular gene delivery in the nonhuman primate."* Although the sample size of eyes undergoing SCS injection of AAV8 expressing green fluorescent protein was small, Dr. Yiu concluded that suprachoroidal injection of AAV8 may be a feasible mode of ocular gene delivery with transduction of mostly retinal pigment epithelium rather than photoreceptors and in peripheral rather than macular regions. In the studies, maximal expression was seen at one month and additional studies are recommended to optimize the extent and duration of viral transduction.

Viral Kansara, Ph.D., Clearside Vice President, Discovery, presented a poster entitled, *"Suprachoroidally delivered non-viral DNA nanoparticles transfect chorioretinal cells in non-human primates and rabbits."* The poster stated that suprachoroidally injected DNA nanoparticles (DNPs) were well tolerated, with luciferase expression/activity in the choroid and retina of rabbit eyes. Most importantly, suprachoroidal administration of luciferase non-viral DNPs produced activity that was comparable to that seen from subretinal injections. In non-human primates, the persistence of luciferase activity was observed through day 22 (last study timepoint) with ellipsoid-shaped DNPs. These studies support further evaluation of suprachoroidally administered non-viral DNA nanoparticle gene therapy.

Uveitis Presentations:

Summary: Ongoing assessment of the Clearside clinical programs for XIPERE continue to demonstrate the potential effectiveness of the agent to treat patients suffering from macular edema secondary to uveitis. Clearside submitted a New Drug Application to the U.S. Food and Drug Administration and has received an October 19, 2019 PDUFA goal date. If approved, XIPERE will be the first therapy indicated for macular edema associated with uveitis.

Eric B. Suhler M.D., M.P.H., Oregon Health and Science University Professor of Ophthalmology and Co-Director, OHSU Uveitis Clinic, gave a presentation at the American Uveitis Society Spring Meeting 2019 entitled, "*Suprachoroidal Administration of Triamcinolone Acetonide (CLS-TA) For the Treatment of Macular Edema in Noninfectious Uveitis: Pooled Results of Three Clinical Trials*." Dr. Suhler pooled the results of three Clearside clinical trials, PEACHTREE, DOGWOOD, and AZALEA, and reported that administration of XIPERE resulted in a rapid (by week 4) and durable (through week 12) reduction in retinal thickness in a majority of subjects following a single suprachoroidal injection. When administered a second injection of XIPERE at week 12, a majority of patients continued to show macular edema resolution through week 24 and did not require additional treatment.

Christopher R. Henry, M.D., Retina Consultants of Houston, presented a poster at ARVO entitled, "*Treatment response analysis of visual acuity and central subfield retinal thickness following suprachoroidal CLS-TA*." Dr. Henry presented a model of the 198 patients treated in PEACHTREE and AZALEA, showing that a typical patient in those trials had a 12-letter improvement in best corrected visual acuity and a 157 micron decrease in central subfield retinal thickness after treatment with XIPERE.

These presentations are available on Clearside's website in the Science section under Programs (http://www.clearsidebio.com/programs.htm#SCIENCE).

About Suprachoroidal Space (SCS) Injection Platform

Clearside's 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 medications, new formulations of medicines, as well as future innovations such as gene therapy.

About XIPERE™

XIPERE™ (triamcinolone acetonide ophthalmic suspension) for Suprachoroidal Injection, formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the back of the eye via suprachoroidal injection for the treatment of macular edema associated with uveitis. Clearside's patented technology is designed to deliver drug to the suprachoroidal space located between the choroid and the outer protective layer of the eye, known as the sclera. Suprachoroidal injection 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, thus potentially providing advantageous and sustained efficacy with a favorable safety profile. A New Drug Application was submitted to the U.S. Food and Drug Administration in December 2018 for XIPERE, and, if approved, XIPERE will be the first therapy indicated for macular edema associated with uveitis.

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

Clearside Biomedical, Inc. is a biopharmaceutical company dedicated to developing treatments that restore and preserve vision for people with serious eye diseases. Clearside's proprietary suprachoroidal treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. The company's unique platform for eye disease treatments is inherently flexible and intended to work with established medicines, new formulations of medicines, as well as future innovations such as gene therapy. Clearside is headquartered in Alpharetta, GA. For more information, please visit http://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 expectations regarding the potential benefits of SCS injection platform, the potential attributes and benefits of Clearside's product candidates and the potential approval and commercialization of XIPERE in the United States. 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, 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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