Clearside Biomedical Announces Multiple Poster Presentations at the Association for Research in Vision and Ophthalmology 2021 Virtual Meeting

May 10, 2021

Presentations support proprietary suprachoroidal space delivery platform and programs

ALPHARETTA, Ga., May 10, 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 that multiple clinical poster presentations related to its suprachoroidal injection platform and programs were delivered at the Association for Research in Vision and Ophthalmology 2021 Virtual Meeting which took place May 1-7, 2021.

“The posters delivered at ARVO are increasingly important as we advance our CLS-AX clinical program and our New Drug Application for XIPERE™ which is under review by the U.S. Food and Drug Administration,” said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer and Chief Development Officer. “The analyses demonstrate the utility of our proprietary suprachoroidal space (SCS®) delivery platform to administer small molecules and gene therapy. The data also continues to validate suprachoroidal delivery as an office-based, repeatable form of administration for therapies for multiple retinal disorders.”

Suprachoroidal Space Delivery Platform

Title: Suprachoroidal injections across species via multimodal imaging

Lead Author: Allen Ho

Conclusions: This project compared suprachoroidal and intravitreal injections using diagnostic imaging and documented three important treatment attributes of suprachoroidal delivery: 1) acute opening of the suprachoroidal space; 2) circumferential, posterior spread of injectate in the suprachoroidal space; and 3) compartmentalization of injectate to posterior tissues away from anterior and corneal tissues. In contrast to intravitreal delivery, suprachoroidal drug delivery targets chorioretinal tissue layers, supporting the potential for more precise delivery to potentially enhance safety and efficacy.

Title: Safety of suprachoroidal injection procedure utilizing a microinjector across three retinal disorders

Lead Author: Sumit Sharma

Conclusions: In this analysis, safety data from the day of the procedure was compiled from 626 patients in eight clinical trials where suprachoroidal injections were performed across three disease states, including non-infectious uveitis, diabetic macular edema, and retinal vein occlusion. Overall, across the eight clinical trials, the safety profile of suprachoroidal injections (SCI), either as monotherapy or in conjunction with intravitreal anti-VEGF injections, is broadly comparable to intravitreal anti-VEGF injections alone.

Title: Ophthalmic Procedure Training During COVID-19: Virtual and In-Person Training of the Suprachoroidal Injection Procedure

Lead Author: Nathan Fisher

Conclusions: An analysis was conducted to evaluate virtual and in-person training modalities in educating retinal specialists and other ophthalmology professionals on performing a suprachoroidal injection with the SCS Microinjector®. Significant travel and site visitation restrictions associated with the COVID-19 pandemic required alternative virtual methodologies be developed to continue training when traditionally utilized in-person wet lab instruction was not permitted. Importantly, physicians who completed virtual or in-person training felt highly confident in their ability to perform the procedure in patients in the future.

Title: Post-Hoc Analysis of Suprachoroidal Injection Experience for Non-Infectious Uveitis

Lead Author: Milan Shah

Conclusions: This study analyzed procedural characteristics of SCIs using the SCS Microinjector from data in two uveitis trials. Both the user survey and the correlation analysis demonstrated that SCIs are well accepted by physician-investigators, and the two needle lengths accommodate a wide range of anatomic and demographic variables. The analysis also concluded that SCIs with the SCS Microinjector have the potential to reliably and repeatably deliver drugs for chorioretinal diseases in an in-office setting.

Treatment burden and unmet needs with current anti-VEGF-A therapies

Title: Longer term visual acuity outcomes and anti-VEGF therapy intensity in neovascular AMD, diabetic macular edema and retina vein occlusion – related macular edema: a real world analysis of 130,247 patient eyes

Lead Author: Thomas Ciulla, MD

Conclusions: In this study, 130,247 patient eyes were assessed from de-identified medical records from hundreds of retina specialists across the United States. The assessment found that “real world” RVO, DME and AMD patients show worse 3- and 5-year anti-VEGF outcomes, compared to 1-year outcomes, that injection frequency plays a large role in visual acuity outcomes, and that AMD patients treated with fewer than 40 injections

within a five-year timeframe lost visual acuity. The study highlights the significant unmet need for more effective and durable therapies to address treatment burden.

Gene Therapy

Title: Suprachoroidally delivered non-viral DNA nanoparticles produce hMyo7A Protein in RPE-choroid in rabbits

Lead Author: Viral Kansara

Conclusions: Functional deficiency of Myosin 7A protein is implicated in the pathogenesis of Usher syndrome, an inherited retinal disease and a form of retinitis pigmentosa. However, adeno-associated viral vectors (AAV) cannot accommodate large genes such as Myo7A, limiting investigational gene therapy for Usher syndrome. The study showed that suprachoroidally delivered DNA nanoparticles containing transgene encoding human Myo7A produced efficient and durable levels of Myosin 7A in RPE-choroid. The data warrant further studies in other species and demonstrated that suprachoroidal delivery has potential as an office-based, repeatable therapy for large-gene disorders.

CLS-TA (XIPERE)

Title: Uveitic macular edema: OCT anatomic and temporal biomarkers

Lead Author: Debra Goldstein

Conclusions: There is limited information on longitudinal structure-functional correlations in uveitic macular edema, the intended indication for CLS-TA. In a post hoc analysis of 198 eyes with uveitic macular edema, this study demonstrated clinically relevant and prognostic relationships between best corrected visual acuity and optical coherence tomography (OCT)-assessed features of macular edema. Importantly, this analysis showed that improvement in macular edema may precede improvement in visual acuity, among patients treated with CLS-TA.

About XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension)

XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for administration to the suprachoroidal space 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 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. Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc. (NYSE/TSX: BHC), has the exclusive license for the commercialization and development of XIPERE in the United States and Canada and an exclusive option for commercialization and development of XIPERE in Europe and the United Kingdom, Australia and New Zealand, and/or South America and Mexico. Arctic Vision, a specialty ophthalmology company based in China, has the exclusive license for the commercialization and development of XIPERE in Greater China and South Korea. XIPERE is not yet approved in any jurisdiction.

About CLS-AX (axitinib injectable suspension)

CLS-AX (axitinib injectable suspension) is a proprietary suspension of axitinib for suprachoroidal injection. Axitinib is a tyrosine kinase inhibitor (TKI) currently approved to treat renal cell cancer that achieves pan-VEGF blockade, directly inhibiting VEGF receptors-1, -2, and -3 with high potency and specificity. Clearside believes this broad VEGF blockade may have efficacy advantages over existing retinal therapies by acting at a different level of the angiogenesis cascade, and may benefit patients who sub-optimally respond to current, more narrowly focused anti-VEGF therapies. Suprachoroidal injection of this proprietary suspension of axitinib has demonstrated meaningful potential in preclinical studies in multiple species. Preclinical results from Clearside and independent investigators have shown pharmacodynamic effects with reduced growth of experimental neovascularization and decreased fluorescein leakage. With suprachoroidal administration of axitinib, there is the potential to achieve prolonged duration and targeted delivery to affected tissue layers. Clearside is developing CLS-AX as a long-acting therapy for the treatment of wet AMD. CLS-AX is currently being investigated in an ongoing US-based, multi-center, open-label, dose-escalation, Phase 1/2a, safety and tolerability study, entitled OASIS, in wet AMD patients, and additional information can be found on https://clinicaltrials.gov (NCT04626128).

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

Clearside's patented, 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 proprietary SCS Microinjector ® can be used to inject a wide variety of drug candidates that are specifically formulated to be delivered via suprachoroidal injection. The SCS Microinjector provides targeted delivery to potentially improve efficacy and compartmentalization of medication to reduce or eliminate toxic effects on non-diseased cells. The SCS Microinjector is composed of a syringe and two 30-gauge hollow microneedles of varying lengths, each less than 1.2 millimeters, within a custom-designed hub that optimizes insertion and suprachoroidal administration of drugs.

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 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 clinical development and the potential benefits of therapies using Clearside's SCS Microinjector ®. 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.

Investor and Media Contacts:

Jenny Kobin
Remy Bernarda
ir@clearsidebio.com
(678) 430-8206

Source: Clearside Biomedical, Inc.