



## Clearside Biomedical Poster Presentation at ARVO 2022 Annual Meeting Demonstrates Versatility of Suprachoroidal Delivery Technology

May 5, 2022

- Multiple Poster Presentations on XIPERE<sup>®</sup> and Gene Therapy Delivery Utilizing SCS Microinjector<sup>®</sup> -

- Dr. Thomas Ciulla to Participate in a Panel Discussion at Retina World Congress 2022 on May 12, 2022 -

ALPHARETTA, Ga., May 05, 2022 (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<sup>®</sup>), announced today that several poster presentations were delivered on Clearside's proprietary suprachoroidal delivery platform, XIPERE<sup>®</sup>, and gene therapy delivery utilizing Clearside's SCS Microinjector<sup>®</sup> at the Association for Research in Vision and Ophthalmology (ARVO) 2022 Annual Meeting.

"Our data presented at ARVO demonstrated that suprachoroidal delivery via our SCS Microinjector<sup>®</sup> enabled targeting, compartmentalization, and durability of small molecule suspensions, thereby potentially addressing some of the efficacy, safety, and treatment burden limitations of current retinal therapies," said Thomas A. Ciulla, M.D., MBA, Chief Medical Officer and Chief Development Officer at Clearside Biomedical. "While our U.S. FDA approval of XIPERE validates our suprachoroidal delivery technology, this is just the beginning. We continue to evaluate additional small molecule suspensions to expand our pipeline while demonstrating the flexibility and versatility of our platform to deliver promising treatments for multiple retinal diseases."

At ARVO, Viral Kansara, PhD, Vice President, Preclinical Development at Clearside Biomedical, presented a poster entitled, "*Targeting, Compartmentalization and Durability of Suprachoroidally Injected Small Molecule Suspensions*" that summarized the preclinical and clinical evaluation of SCS Microinjector-based suprachoroidal (SC) delivery, and its synergy with small molecule suspensions for a potentially safe, efficacious and durable ocular delivery platform. The studies showed several key findings:

- SC injected small molecule suspensions, at studied dose levels and duration, were well-tolerated in rabbits.
- *Ex-vivo* and *in-vivo* imaging confirmed posterior spread and opening of the SCS immediately after the SC injection.
- SC injected small molecule suspensions achieved high and durable drug levels in the retina and retina-choroid-sclera.
- SC injected small molecule suspensions demonstrated targeted and compartmentalized drug levels to the chorioretina, and low to minimal drug exposure in the lens, vitreous humor, and aqueous humor.
- SC injected axitinib and triamcinolone acetonide suspensions demonstrated signs of biological activities in preclinical animal models and in the clinic.

### **Partner Presentations**

Several posters were presented at ARVO related to XIPERE<sup>®</sup> (triamcinolone acetonide injectable suspension) for suprachoroidal use:

- "*National Physician Survey on Clinical Practice Patterns for the Treatment of Noninfectious Uveitis.*" Cavet et al.
- "*Suprachoroidal Triamcinolone Acetonide Injectable Suspension for Macular Edema Associated with Uveitis: Effect of Disease Characteristics on Clinical Outcomes.*" Singer et al.
- "*Suprachoroidal Triamcinolone Acetonide Injectable Suspension for Macular Edema Associated with Uveitis: Integrated Analysis of Two Clinical Trials.*" Yeh et al.
- "*Suprachoroidal Triamcinolone Acetonide Injectable Suspension for Macular Edema Associated with Uveitis: Outcomes by Anatomic Subtypes in PEACHTREE.*" Nguyen et al.
- "*Suprachoroidal Triamcinolone Acetonide Injectable Suspension for Macular Edema Associated with Uveitis: Visual and Anatomic Outcomes by Age.*" Henry et al.

Two presentations were delivered on REGENXBIO asset RGX-314 administered via Clearside's SCS Microinjector:

- "*Suprachoroidal Delivery of RGX-314 Gene Therapy for Neovascular AMD: The Phase II AAVIATE™ Study*"
- "*Suprachoroidal Delivery of RGX-314 for Diabetic Retinopathy: The Phase II ALTITUDE™ Study*"

### **Retina World Congress 2022**

Dr. Ciulla will also be participating in two events at the [Retina World Congress 2022](#) conference taking place May 12-15, 2022, in Fort Lauderdale Florida.

- Thursday, May 12, 2022 at 10:20 am – 11:00 am EDT: Panelist, "New Pathways in Retinal Diseases"
- Thursday, May 12, 2022 at 5:36 pm – 5:44 pm EDT: Presentation, "Longer-term Visual Acuity Outcomes and Anti-VEGF Therapy Intensity in Neovascular AMD, DME, and RVO-Related Macular Edema: A Real-World Analysis of 130,247"

### About Clearside’s Suprachoroidal Space (SCS<sup>®</sup>) Injection Platform and SCS Microinjector<sup>®</sup>

Clearside’s patented, proprietary suprachoroidal space (SCS) injection platform offers unprecedented access to the back of the eye where sight-threatening disease often occurs. 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. 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 into the SCS. 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, with a custom-designed hub that optimizes insertion and suprachoroidal administration of drugs.

### About XIPERE<sup>®</sup> (triamcinolone acetonide injectable suspension) for suprachoroidal use

XIPERE<sup>®</sup> (triamcinolone acetonide injectable suspension) for suprachoroidal use, formerly known as CLS-TA, is a proprietary suspension of the corticosteroid triamcinolone acetonide for administration to the suprachoroidal space for the treatment of macular edema associated with uveitis. Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc., has the exclusive license for the commercialization and development of XIPERE in the United States 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 Arcatus™, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. XIPERE was approved by the U.S. Food and Drug Administration in October 2021 and is commercially available in the U.S.

### Important Safety Information about XIPERE<sup>®</sup>

#### Indication

XIPERE<sup>®</sup> (triamcinolone acetonide injectable suspension) for suprachoroidal use is a corticosteroid indicated for the treatment of macular edema associated with uveitis.

#### IMPORTANT SAFETY INFORMATION

Patients should be monitored following injection for elevated intraocular pressure. See Dosage and Administration instructions in full Prescribing Information.

- XIPERE is contraindicated in patients with **active or suspected ocular or periocular infections** including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.
- XIPERE is contraindicated in patients with known **hypersensitivity to triamcinolone acetonide** or any other components of this product.
- Use of corticosteroids may produce cataracts, increased intraocular pressure, and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses, and should be used cautiously in patients with a history of ocular herpes simplex.
- Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing’s syndrome, and hyperglycemia can occur following administration of a corticosteroid. Monitor patients for these conditions with chronic use.
- In controlled studies, the most common ocular adverse reactions were increased ocular pressure, non-acute (14%), eye pain, non-acute (12%), cataract (7%); increased intraocular pressure, acute (6%), vitreous detachment (5%), injection site pain (4%) conjunctival hemorrhage (4%), visual acuity reduced (4%), dry eye (3%), eye pain, acute (3%), photophobia (3%), and vitreous floaters (3%), and in 2% of patients: uveitis, conjunctival hyperaemia, punctate keratitis, conjunctival oedema, meibomianitis, anterior capsule contraction, chalazion, eye irritation, eye pruritus, eyelid ptosis, photopsia, and vision blurred.

The most common non-ocular adverse event was headache (5%).

- Corticosteroids should be used during pregnancy or nursing only if the potential benefit justifies the potential risk to the fetus or nursing infant.

To report **SUSPECTED ADVERSE REACTIONS**, contact Bausch + Lomb at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please [click here](#) for full Prescribing Information.

### About Clearside Biomedical

Clearside Biomedical, Inc. is a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS<sup>®</sup>). Clearside’s SCS injection platform, utilizing the Company’s proprietary SCS Microinjector<sup>®</sup>, 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 and strategically partners its SCS injection platform with companies utilizing other ophthalmic

therapeutic innovations. Clearside's first product, [XIPERE®](#) (triamcinolone acetonide injectable suspension) for suprachoroidal use, is commercially available in the U.S. For more information, please visit [www.clearsidebio.com](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 statements regarding 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, 2021, filed with the U.S. Securities and Exchange Commission (SEC) on March 11, 2022, 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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