



## Clearside Biomedical Asia-Pacific Partner Arctic Vision Announces the Acceptance in Australia of its New Drug Application for Suprachoroidal Use of Arcatus® for the Treatment of Uveitic Macular Edema

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*- XIPIRE® is referred to as Arcatus (ARVN001) by Arctic Vision –*

ALPHARETTA, Ga., July 10, 2023 (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®), announced that the Therapeutic Goods Administration (TGA) of Australia has formally accepted Arctic Vision's new drug application (NDA) for suprachoroidal use of Arcatus® (ARVN001) for the treatment of Uveitic Macular Edema. Arctic Vision is a specialty ophthalmology company based in China that has the exclusive license for the commercialization and development of XIPIRE®, which they refer to as Arcatus, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries.

"Acceptance of the NDA in Australia is additional validation of suprachoroidal administration as an innovative, recognized form of ophthalmic drug delivery and another step towards the global commercialization of XIPIRE," said George Lasezkay, Pharm.D., J.D., President and Chief Executive Officer of Clearside. "With approval in the U.S., regulatory review ongoing in Australia, and plans to gradually submit applications in more countries in its territories, our partner Arctic Vision continues to expand access for patients to the only product approved for the treatment of 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 XIPIRE® (triamcinolone acetonide injectable suspension) for suprachoroidal use

XIPIRE® (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 company dedicated to helping people see better to live better, has the exclusive license for the commercialization and development of XIPIRE 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 XIPIRE, which they refer to as Arcatus®, in Greater China, South Korea, Australia, New Zealand, India and the ASEAN Countries. XIPIRE 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 XIPIRE®

#### Indication

XIPIRE® (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.

- XIPIRE 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.
- XIPIRE 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, Inc.**

Clearside Biomedical, Inc. is a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®). Clearside's SCS injection platform, utilizing the Company's patented 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. The Company's lead program, CLS-AX (axitinib injectable suspension), for the treatment of neovascular age-related macular degeneration (wet AMD), is in Phase 2b clinical testing. Clearside developed and gained approval for its first product, [XIPERE® \(triamcinolone acetonide injectable suspension\)](#) for suprachoroidal use, which is available in the U.S. through a commercial partner. Clearside also strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. For more information, please visit [clearsidebio.com](http://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 of CLS-AX, the number of sites for the ODYSSEY Phase 2b clinical trial for CLS-AX, the expected timing of topline results from the ODYSSEY clinical trial, and the potential benefits of CLS-AX and other product candidates using Clearside's SCS Microinjector<sup>®</sup>. 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, 2022, filed with the U.S. Securities and Exchange Commission (SEC) on March 14, 2023 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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