

# Bausch + Lomb and Clearside Biomedical Announce the U.S. Commercial Launch of XIPERE® (Triamcinolone Acetonide Injectable Suspension) For Suprachoroidal Use for the Treatment of Macular Edema Associated with Uveitis

March 28, 2022

## **XIPERE® is the First and Only FDA-Approved Therapy for Delivery via Suprachoroidal Injection**

LAVAL, QC and ALPHARETTA, Ga., March 28, 2022 /PRNewswire/ -- Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health"), and Clearside Biomedical, Inc. (Nasdaq: CLSD) ("Clearside"), a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®), today announced the U.S. commercial launch of XIPERE® (triamcinolone acetonide injectable suspension), the first and only therapy approved by the U.S. Food and Drug Administration (FDA) for suprachoroidal use for the treatment of macular edema associated with uveitis, a form of eye inflammation.<sup>1</sup>

"XIPERE® is the first and only therapy available in the United States that utilizes the suprachoroidal space to treat patients who struggle with macular edema associated with uveitis, which is the leading cause of vision loss in people with uveitis<sup>2</sup>," said Joseph C. Papa, chairman and CEO, Bausch Health. "Throughout the past several months, we have been training eye care professionals all over the country on how to properly administer XIPERE® using its unique suprachoroidal injection method, which enables targeted delivery and compartmentalization of the medication. We are pleased that XIPERE® is now broadly available as a new and unique treatment option for the 300,000 Americans who suffer from this serious condition."<sup>3</sup>

Macular edema is the buildup of fluid in the macula, which causes retinal swelling and distorted vision, and if left untreated, may lead to permanent vision loss.<sup>4</sup> XIPERE® is approved for the treatment of macular edema associated with uveitis via suprachoroidal administration using the proprietary SCS Microinjector® developed by Clearside.

"The commercialization of XIPERE® is an exciting step forward for the treatment of macular edema associated with uveitis, and also for increasing education and recognition of the suprachoroidal space as a highly effective administration route for back-of-the-eye therapies," said George Lasezkay, Pharm.D., J.D., president and CEO, Clearside. "As the first commercial product developed by Clearside and the first therapy approved for macular edema associated with uveitis, XIPERE® represents our commitment to delivering much needed treatments for those living with serious retinal diseases."

Suprachoroidal administration is an innovative approach for delivering ocular therapies that may facilitate more targeted delivery of therapeutic agents to the retina and choroid. The

suprachoroidal space is located between the sclera and the choroid, which expands upon injection, allowing delivery of XIPERE<sup>®</sup> to the posterior structures of the eye.<sup>5</sup>

"Suprachoroidal administration, which provides exceptional access and high bioavailability to the posterior segment of the eye, has been well tolerated by patients," said Steven Yeh, M.D., professor of Ophthalmology and director of Retinal Disease and Uveitis, Stanley M. Truhlsen Eye Institute, University of Nebraska Medical Center, and principal investigator for the XIPERE<sup>®</sup> Phase 3 pivotal study. "This administration technique is unlike traditional intraocular administration, and therefore, training for how to properly inject patients with this new medicine is important. I encourage eye care professionals to take advantage of the trainings being offered by Bausch + Lomb."

Physicians interested in attending a XIPERE<sup>®</sup> training session can register at

<https://www.xipere.com/hcp/xipere-training>

. For more information on XIPERE<sup>®</sup>, visit

[www.xipere.com](http://www.xipere.com)

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

### **INDICATION**

XIPERE<sup>®</sup> (triamcinolone acetonide injectable suspension) is a corticosteroid used to treat macular edema associated with an eye disease called uveitis.

### **IMPORTANT SAFETY INFORMATION**

- Your eye doctor will monitor you for elevated eye pressure following treatment and manage it with medication or surgery if required.
- See your eye doctor right away if your eyes become red, sensitive to light or painful, or if you notice changes in vision.
- XIPERE is not appropriate for use in patients with eye infections. It should be used with caution in patients with a history of herpes simplex in the eye.
- XIPERE is not appropriate for use in patients with a known allergy to triamcinolone acetonide or any other components of this product.
- Use of corticosteroids such as XIPERE may produce cataracts, increased eye pressure and glaucoma, and may increase the likelihood of eye infections.
- Patients being treated with XIPERE for extended periods of time will be monitored for problems with the body's hormonal system, which controls the ability to respond to stress.
- In clinical studies, the most common eye-related side effects were increased eye pressure and eye pain. Other side effects included cataract, floaters or flashes of light, injection site pain, burst blood vessels, reduced or blurred vision, dry eye, light sensitivity, redness, infection, swelling, watery eyes, eye or eyelid irritation, bumps on the eyelid, itchy eyes, and drooping eyelid.

The most common non-eye-related side effect was headache.

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

**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)

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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. For more information, please visit

[www.clearsidebio.com](http://www.clearsidebio.com)

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### **About Bausch + Lomb**

Bausch + Lomb, a leading global eye health business of Bausch Health Companies, Inc., is dedicated to protecting and enhancing the gift of sight for millions of people around the world – from the moment of birth through every phase of life. Its comprehensive portfolio of more than 400 products includes contact lenses, lens care products, eye care products, ophthalmic pharmaceuticals, over-the-counter products and ophthalmic surgical devices and instruments. Founded in 1853, Bausch + Lomb has a significant global research and development, manufacturing and commercial footprint with more than 12,000 employees and a presence in nearly 100 countries. Bausch + Lomb is headquartered in Vaughan, Ontario with corporate offices in Bridgewater, New Jersey. For more information, visit

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### **About Bausch Health**

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. For more information, visit

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### **Clearside Biomedical 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 commercial launch of XIPERE. 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 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.

### **Bausch Health Forward-looking Statements**

This news release may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties discussed in Bausch Health's most recent annual report on Form 10-K and detailed from time to time in Bausch Health's other filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. They also include, but are not limited to, risks and uncertainties caused by or relating to the evolving COVID-19 pandemic, and the fear of that pandemic and its potential effects, the severity, duration and future impact of which are highly uncertain and cannot be predicted, and which may have a material adverse impact on Bausch Health, including but not limited to its project development timelines, launches and costs (which may increase). Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Bausch Health undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

### **References**

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**XIPERE**<sup>®</sup>  
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injectable suspension) 40 mg/mL



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SOURCE Bausch Health Companies Inc.; Clearside Biomedical, Inc.



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