BAUSCH Health

Bausch + Lomb and Clearside Biomedical Announce FDA Approval of XIPERE™ (triamcinolone acetonide injectable suspension) for Suprachoroidal Use for the Treatment of Macular Edema Associated with Uveitis

October 25, 2021

XIPERE™ is the First and Only Medicine to be Approved in the United States for Delivery via Suprachoroidal Injection, a Method Designed to Facilitate Targeted Delivery of Therapeutic Agents to the Retina and Choroid

LAVAL, QC and ALPHARETTA, Ga., Oct. 25, 2021 /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 that the U.S. Food and Drug Administration (FDA) has approved XIPERE™ (triamcinolone acetonide injectable suspension) for suprachoroidal use for the treatment of macular edema associated with uveitis, a form of eye inflammation[1].

"With this FDA approval, XIPERE™ is the first and only therapy available in the United States that utilizes the suprachoroidal space to treat patients suffering from macular edema associated with uveitis, which is the leading cause of vision loss in people with uveitis[2]. The utilization of the suprachoroidal space provides targeted delivery and compartmentalization of medication," said Joseph C. Papa, chairman and CEO, Bausch Health. "The approval of XIPERE™ exemplifies our commitment to bringing innovative new options to help patients improve their treatment journey. We expect to make XIPERE™ available during the first quarter of 2022."

"The suprachoroidal space is an untapped frontier in eye health. We are proud to be the pioneers in treating serious retinal diseases by implementing this novel, targeted approach. With this approval, we begin a new era in delivering therapies to the back of the eye," said George Lasezkay, Pharm.D., J.D., president and CEO, Clearside. "XIPERE™ is the first commercial product developed by Clearside, the first product approved for injection into the suprachoroidal space and the first therapy approved for macular edema associated with uveitis. Our unique approach now has the potential to positively impact this patient population, which previously had no other treatment options approved for this indication."

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[3]. XIPERE™ is designed to treat macular edema associated with uveitis via suprachoroidal administration using the proprietary SCS Microinjector® developed by Clearside. Suprachoroidal administration is an innovative technique for delivering ocular therapies that may facilitate more targeted delivery of therapeutic agents to the retina and choroid.

The SCS Microinjector® offers unique access to the back of the eye where sight-threatening disease often occurs. It is designed to provide targeted and compartmentalized delivery and

higher proportions of absorption relative to intravitreal injection (IVT)[4]. Targeted drug delivery via the suprachoroidal space (SCS®) may also limit corticosteroid exposure to the anterior segment[5] with the potential to reduce the risk of certain adverse events, such as cataracts, intraocular pressure elevation and exacerbation of glaucoma, that are commonly associated with local delivery techniques[6].

"The safety and efficacy data of XIPERE™ was demonstrated in multiple clinical studies and its unique suprachoroidal administration approach provides exceptional access and high bioavailability to the posterior segment of the eye," 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™ Phase 3 (PEACHTREE) pivotal study. "With the approval of XIPERE™, eye care professionals now have a new and innovative treatment option for their patients with macular edema associated with uveitis."

XIPERE™ Clinical Data
The clinical program for XIPERE™ included the pivotal Phase 3 trial (PEACHTREE), a Phase 3, multi-center, non-interventional extension study (MAGNOLIA), and an open-label safety trial (AZALEA).

The FDA approval of XIPERE™ was based on results from PEACHTREE, a randomized, multicenter, double-masked, sham-controlled Phase 3 clinical trial of 160 patients with macular edema associated with uveitis. XIPERE™ is the first and only uveitic macular edema treatment to demonstrate clinical efficacy with a BCVA (Best Corrected Visual Acuity) primary endpoint.

The primary efficacy endpoint was the proportion of patients in whom BCVA had improved by at least 15 letters from baseline after 24 weeks of follow-up. In the trial, a statistically significantly greater proportion of patients treated with XIPERE™ (47%) achieved at least a 15-letter improvement in BCVA than patients in the control arm (16%, $p < 0.01$) at Week 24[7].

The most common adverse reactions reported by greater than or equal to 10% of patients and at a rate greater than control included elevated intraocular pressure and eye pain.

Important Safety Information about XIPERE™

Indication
XIPERE™ (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 orsuspected 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%), cataract (7%), 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit
www.fda.gov/medwatch
or call 1-800-FDA-1088.

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®). Clearside's SCS injection platform, utilizing the Company's proprietary SCS Microinjector®, 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
.

About Bausch + Lomb
Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc., is solely focused on helping people see. Its core businesses include over-the-counter products, dietary supplements, eye care products, ophthalmic pharmaceuticals, contact lenses, lens care products, ophthalmic surgical devices and instruments. Bausch + Lomb develops, manufactures and markets one of the most comprehensive product portfolios in the industry, which is available in approximately 100 countries. More information can be found at
www.bausch.com
.

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
www.bauschhealth.com
and connect with us on
Twitter
and
LinkedIn
.

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 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 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.

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

- XIPERE™ [prescribing information]. Alpharetta, GA: Clearside Biomedical, Inc.; 2021.
- Massa, H., Pipis, S. Y., Adewoyin, T., Vergados, A., Patra, S., & Panos, G. D. (2019). Macular edema associated with non-infectious uveitis: pathophysiology, etiology, prevalence, impact and management challenges. Clinical ophthalmology (Auckland, N.Z.), 13, 1761–1777.

https://doi.org/10.2147/OPTH.S180580
.

- American Academy of Ophthalmology. Retrieved from https://www.aao.org/eye-health/diseases/what-is-macular-edema . Accessed August 20, 2021.
- Viral S. Kansara, Leroy W. Muya, Thomas A. Ciulla; Evaluation of Long-Lasting Potential of Suprachoroidal Axitinib Suspension Via Ocular and Systemic Disposition in Rabbits. *Trans. Vis. Sci. Tech.* 2021;10(7):19. doi: https://doi.org/10.1167/tvst.10.7.19 .
- Chiang B, Jung JH, Prausnitz MR. The suprachoroidal space as a route of administration to the posterior segment of the eye. *Adv Drug Deliv Rev*. 2018;126:58-66. doi:10.1016/j.addr.2018.03.001.
- Moisseiev E, Loewenstein A, Yiu G. The suprachoroidal space: from potential space to a space with potential. *Clin Ophthalmol*. 2016;10:173-178. Published 2016 Jan 25. doi:10.2147/OPTH.S89784.
- Yeh, S., Khurana, R. N., Shah, M., Henry, C. R., Wang, R. C., Kissner, J. M., Ciulla, T. A., & Noronha, G. (2020). Efficacy and safety of suprachoroidal CLS-TA for macular edema secondary to noninfectious uveitis. Ophthalmology, 127(7), 948–955. https://doi.org/10.1016/j.ophtha.2020.01.006 .

XIPERE™, suprachoroidal space (SCS®), and SCS Microinjector® are trademarks of Clearside Biomedical used under license.
Any other product/brand names and/or logos are trademarks of the respective owners.
© 2021 Bausch & Lomb Incorporated or its affiliates.
XIP.0048.USA.21

Clearside Investor and Media Contacts:
Jenny Kobin
Remy Bernarda
ir@clearsidebio.com
(678) 430-8206

Bausch Health Investor Contact:
Arthur Shannon
arthur.shannon@bauschhealth.com

(514) 865-3855
(877) 281-6642 (toll free)

Bausch Health Media Contact:
Lainie Keller
lainie.keller@bauschhealth.com

(908) 927-1198

XIPERE™
(triamcinolone acetonide injectable suspension) 40 mg/mL

BAUSCH + LOMB

CLEARSIDE® BIOMEDICAL

BAUSCH Health

C

View original content to download multimedia: https://www.prnewswire.com/news-releases/bausch--lomb-and-clearside-biomedical-announce-fda-approval-of-xipere-triamcinolone-acetonide-injectable-suspension-for-suprachoroidal-use-for-the-treatment-of-macular-edema-associated-with-uveitis-301407260.html

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

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
848-264-0934

LEGAL NOTICE PRIVACY POLICY

EMAIL ALERTS EMAIL PAGE RSS FEED

Use of this site signifies your agreement to the Legal Notice and Privacy Policy.
©2026 Bausch Health Companies Inc. All rights reserved. MTB.0230.USA.18 V2.0

CALIFORNIA RESIDENTS: DO NOT SELL MY PERSONAL INFORMATION

Powered by SITECORE