Bausch Health And Clearside Biomedical Announce U.S. FDA Filing Acceptance For XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension)

June 02, 2021

PDUFA Action Date Is October 30, 2021

LAVAL, QC and ALPHARETTA, Ga., June 2, 2021 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and Bausch + Lomb, its leading global eye health business, along with Clearside Biomedical, Inc. (Nasdaq: CLSD) ("Clearside"), 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 the U.S. Food and Drug Administration (FDA) has accepted the resubmitted New Drug Application for XIPERE™[1] (triamcinolone acetonide suprachoroidal injectable suspension). FDA determined that the filing is a Class 2 resubmission and therefore assigned a Prescription Drug User Fee Act (PDUFA) action date of October 30, 2021. XIPERE is an investigational therapy with a proposed indication of treatment of macular edema associated with uveitis.

"The FDA's filing acceptance for XIPERE is an exciting milestone for our collaboration with Clearside. If approved by the FDA, XIPERE would be the first therapy available utilizing the suprachoroidal space for patients suffering from macular edema associated with uveitis, which is the leading cause of vision loss in people with uveitis. With this acceptance, we are one step closer to providing an important novel treatment option for this patient population," said Joseph C. Papa, chairman and CEO, Bausch Health.

"XIPERE has the potential to advance the care of people suffering from macular edema with uveitis," said George Lasezkay, Pharm.D., J.D., president and CEO, Clearside. "If approved, XIPERE would be our first commercial product and the first approved drug to be delivered into the suprachoroidal space (SCS®). We are committed to continuing the important work with Bausch Health to help bring forward this important potential treatment option for patients and eye care professionals in the United States."

XIPERE is designed for suprachoroidal administration via Clearside's patented, proprietary SCS Microinjector® that offers unprecedented access to the back of the eye where sight-threatening disease often occurs. The SCS Microinjector provides targeted delivery to potentially improve efficacy and compartmentalization of medication. Targeted drug delivery via the suprachoroidal space may also limit corticosteroid exposure to the anterior segment with the potential to reduce the risk of certain adverse events, such as cataracts, intraocular pressure elevation and exacerbation of glaucoma, that can commonly arise from other local corticosteroid delivery techniques.

About XIPERE™

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 that is being investigated 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 and adequate 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. An affiliate of Bausch Health acquired the exclusive license for the commercialization and development of XIPERE in the United States and Canada in October 2019. The Bausch Health affiliate also has exclusive options for the right to commercialize and develop XIPERE in the European Union, 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 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® targeting the suprachoroidal space (SCS®) 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, as well as future therapeutic innovations such as gene therapy. For more information, please visit
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 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. 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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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," "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 ("SEC") 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, 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.

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 potential benefits of XIPERE and Clearside's SCS Microinjector® as well as the timing of potential FDA approval of the NDA resubmission. 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.

[1] *Provisional name*

Any product/brand names are trademarks of the respective owners.
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