Bausch Health Licenses Clearside Biomedical's XIPERE™ (Triamcinolone Acetonide Suprachoroidal Injectable Suspension), An Investigational Treatment For Macular Edema Associated With Uveitis

October 23, 2019

NDA Resubmission to the FDA Expected to Occur in the First Quarter of 2020

LAVAL, Quebec and ALPHARETTA, Ga., Oct. 23, 2019 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and Bausch + Lomb, its leading global eye health business, and Clearside Biomedical, Inc. (Nasdaq: CLSD) ("Clearside"), a biopharmaceutical company dedicated to developing and delivering treatments that can restore and preserve vision for people with serious back of the eye diseases, announced today that an affiliate of Bausch Health has acquired an exclusive license for the commercialization and development of XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) in the United States and Canada.

XIPERE is a proprietary suspension of the corticosteroid triamcinolone acetonide formulated for suprachoroidal administration via Clearside's proprietary SCS Microinjector™ that is being investigated as a targeted treatment of macular edema associated with uveitis. Clearside expects to resubmit its New Drug Application (NDA) for XIPERE to the U.S. Food and Drug Administration (FDA) for review in the first quarter of 2020 and believes the FDA will review the NDA within six months of receipt of the resubmission.

"Bausch Health is committed to continuing our pivot to offense by augmenting our pipeline with investigational treatments like XIPERE, which we believe will complement our Bausch + Lomb portfolio of integrated eye health products," said Joseph C. Papa, chairman and CEO, Bausch Health. "If approved by the FDA, XIPERE will be the first therapy available for patients suffering from macular edema associated with uveitis."

"We believe that partnering with Bausch + Lomb will allow us to maximize XIPERE's commercial potential and provide broad accessibility for patients," said George Lasezkay, Pharm.D., J.D., CEO of Clearside. "With an established and experienced ophthalmic sales force, we believe Bausch + Lomb can quickly and efficiently integrate XIPERE into their commercial operations. We look forward to coordinating with the Bausch + Lomb team to gain regulatory approval and to share key learnings from our physician training program to help ensure a successful launch of XIPERE in the United States and Canada."

Under the terms of the agreement, Clearside will receive up to $20 million in payments prior to launch, including an upfront payment upon signing the agreement. Clearside may receive additional payments based on certain sales-based milestones and regulatory approvals for additional indications of the XIPERE product. Clearside also will be entitled to receive tiered royalties based on annual net sales of XIPERE in the United States and Canada.

Bausch Health also has the right to pursue development and commercialization of XIPERE for additional ophthalmic indications in the United States and Canada. Furthermore, Bausch Health has the right to develop and commercialize Clearside's proprietary SCS Microinjector in combination with certain specified corticosteroids and NSAIDs in the United States and Canada for the field of ophthalmology.

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 back of the eye 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.

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
www.clearsidebio.com
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About Bausch + Lomb

Bausch + Lomb, a Bausch Health Companies Inc. company, is a leading global eye health organization that 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
www.bausch.com
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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. More information can be found at
www.bauschhealth.com
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Clearside 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 timing for resubmitting the XIPERE NDA and the FDA's review of the resubmitted NDA, maximizing XIPERE's

commercial potential and providing broad accessibility for patients and Bausch + Lomb's ability to successfully launch XIPERE in the United States and Canada. 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, 2018, filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2019, Clearside's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the SEC on August 8, 2019, 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's Cautionary Note Regarding 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," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. Where applicable, these statements are based upon the current expectations and beliefs of Bausch Health 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, risks and uncertainties discussed in the Bausch Health's most recent annual or quarterly report and detailed from time to time in the Bausch Health's other filings with the SEC and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. Bausch Health believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but 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.

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