Bausch Health and Clearside Biomedical Announce Publication of PIVOTAL Phase 3 Data ON XIPERETM (triamcinolone acetonide suprachoroidal injectable suspension) in Ophthalmology

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LAVAL, Quebec and ALPHARETTA, Ga., Jan. 28, 2020 /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), 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 *Ophthalmology*, the peer-reviewed journal of the American Academy of Ophthalmology, has published results from the randomized, controlled, double-masked Phase 3 clinical trial (PEACHTREE study) of XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension), an investigational therapy with a proposed indication of treatment of macular edema associated with uveitis.[1]

"Macular edema is the leading cause of vision loss in patients with uveitis," said Steven Yeh, M.D., lead author and principal investigator for the PEACHTREE study, and M. Louise Simpson Associate professor of ophthalmology, Emory Eye Center. "The efficacy and safety data from the PEACHTREE Phase 3 trial showed that delivery of XIPERE via suprachoroidal administration, an alternative technique for delivering ocular therapies, may facilitate more targeted delivery of therapeutic agents to the retina and choroid. Targeted drug delivery via the suprachoroidal space may also limit corticosteroid exposure to the anterior segment with the potential to decrease adverse events, such as cataracts, intraocular pressure elevation and exacerbation of glaucoma, that can commonly arise from other local corticosteroid delivery techniques."

The data demonstrated that patients with noninfectious uveitis in the XIPERE study arm experienced clinically significant improvement in vision relative to the control arm, demonstrating the potential efficacy of suprachoroidal injection of XIPERE for the treatment of macular edema associated with uveitis. No serious adverse events (AEs) considered by the investigators related to treatment were reported.

"The publication of our positive Phase 3 XIPERE clinical trial results is an important milestone for Clearside as it expands the understanding of our suprachoroidal treatment approach," said Thomas A. Ciulla, M.D., MBA, chief medical officer, Clearside Biomedical. "We are coordinating closely with Bausch Health, our exclusive licensee of XIPERE in the United States and Canada, and are excited for the potential to add this treatment option to the repertoire for retinal specialists."

"We are encouraged by the results of these data as they demonstrated clinically meaningful improvement in vision for nearly half of the patients treated, further supporting the efficacy profile of XIPERE," said Joseph C. Papa, chairman and CEO, Bausch Health. "We look forward to continuing to advance this promising therapy with Clearside, and we are hopeful that, if approved, we will quickly bring forward this potential new treatment option for patients."

About the Phase 3 PEACHTREE Study
The PEACHTREE study was a randomized, controlled, masked, Phase 3 clinical trial that evaluated the safety and efficacy of XIPERE in 160 patients with macular edema associated with noninfectious uveitis. Patients were randomized to receive XIPERE at baseline and at 12 weeks versus control. The PEACHTREE study met its primary endpoint, with 47 percent of patients in the XIPERE arm gaining at least 15 letters in best corrected visual acuity from baseline at week 24, compared to 16 percent of patients in the control arm ($p<0.001$), using the standardized Early Treatment of Diabetic Retinopathy Study scale (visual acuity testing). All key secondary and additional endpoints of the PEACHTREE study were also achieved. No serious AEs considered by the investigators to be related to treatment were reported. Corticosteroid-associated AEs of elevated intraocular pressure occurred in 11.5% and 15.6% of the XIPERE and control groups, respectively. Cataract AE rates were comparable (7.3% and 6.3%, respectively).

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. 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.

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.

About Bausch + Lomb
Bausch + Lomb, the 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 more than 100 countries. For more information, visit 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. More information can be found at www.bauschhealth.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 timing for resubmitting the XIPERE NDA, the potential approval of XIPERE for the treatment of macular edema associated with uveitis, opportunities for expanding Clearside's internal pipeline, and the potential benefits of XIPERE and the SCS injection platform. 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 September 30, 2019, filed with the SEC on November 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 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 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 Bausch Health's most recent annual or quarterly report 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. 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:
1. Steven Y, et al. Efficacy and Safety of Suprachoroidal CLS-TA for Macular Edema Secondary to Noninfectious Uveitis: Phase 3, Randomized Trial. *Ophthalmology*. 2020: *doi:10.1016/j.ophtha.2020.01.006.*

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