# Clearside Biomedical Revises NDA Resubmission Timeline and XIPERE™ Commercial Partnership with Bausch Health

April 28, 2020

*- Management to Host Webcast and Conference Call Today at 8:30 A.M. ET -*

ALPHARETTA, Ga., April 28, 2020 (GLOBE NEWSWIRE) -- 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 an update to the XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension) New Drug Application (NDA) resubmission timeline and to its commercialization and development partnership with Bausch Health Companies Inc. ("Bausch Health") and Bausch + Lomb, its leading global eye health business.

As previously disclosed, the contract manufacturing organization (CMO) for XIPERE has been completing certain requalification activities within its facility. While these manufacturing activities are not specifically related to XIPERE, the CMO has advised Clearside that they continue to impact the timing of its production. Although extensive progress has been made, the CMO needs to resolve a final step affecting the proper functioning of its filling line equipment in order to produce the required stability batches to generate the data necessary for the XIPERE NDA resubmission. As a result, and due in part to COVID-19 related challenges that have impacted work schedules, the CMO has informed Clearside that there will be a delay in completing the necessary corrective action. Based on this current information, Clearside now expects to resubmit the XIPERE NDA in the fourth quarter of 2020.

In conjunction with this update, Clearside and Bausch Health have amended and revised their partnership for XIPERE. Bausch + Lomb acquired an exclusive license in October 2019 for the commercialization and development of XIPERE in the United States and Canada. Bausch + Lomb has now been granted exclusive options for the right to commercialize and develop XIPERE in (i) Europe and the United Kingdom, (ii) Australia and New Zealand, and (iii) South America and Mexico. In the amended agreement, Bausch + Lomb has extended the time allowed for Clearside to obtain XIPERE approval in the United States.

"We remain firmly committed to receiving approval from the U.S. Food and Drug Administration for XIPERE as a potential treatment option for patients suffering from macular edema associated with uveitis," said George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer. "We have been working collaboratively with Bausch Health throughout this process and they have proven to be the ideal partner. We are pleased that their continued support of XIPERE and their interest in our suprachoroidal space (SCS®) injection platform has resulted in an opportunity to expand our relationship to maximize the commercial potential for XIPERE in additional important territories around the world."

"Our other pipeline programs and external collaborations are not impacted by this timing, as there are separate CMOs for the SCS Microinjector®, CLS-AX (axitinib injectable suspension), and other compounds to be used in various clinical trials by our partners. We remain on track to submit an Investigational New Drug (IND) application in mid-2020 for CLS-AX in wet age-related macular degeneration, which would potentially enable us to initiate a Phase 1/2a clinical trial before the end of this year. We also expect a number of IND submissions in 2020 from our clinical development partners in gene therapy and ocular cancer utilizing our SCS Microinjector," concluded Dr. Lasezkay.

As of March 31, 2020, Clearside's cash and cash equivalents totaled $20.9 million. Based on Clearside's current research and development plans and expected near-term partnership milestone payments, Clearside believes it will have sufficient resources to fund its planned operations into the second quarter of 2021. Detailed financial results for the quarter will be reported via a press release on May 8, 2020.

Management will host a webcast and conference call today at 8:30 a.m. Eastern Time to discuss this announcement and provide an update on the Company's clinical development pipeline. The live and archived webcast may be accessed on the Clearside website under the Investors section: Events and Presentations. The live call can be accessed by dialing (844) 263-8310 (domestic) or (213) 358-0959 (international) and entering conference code: 5612638.

**About XIPERE™ (triamcinolone acetonide suprachoroidal injectable suspension)**

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 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. Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc., has the exclusive license for the commercialization and development of XIPERE in the United States and Canada and an exclusive option for Europe and the United Kingdom, Australia and New Zealand, and South America and Mexico (through a license agreement between Clearside and Bausch Health's affiliate). 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.

**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.

**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 timelines for resubmitting the NDA for XIPERE and submitting the IND for CLS-AX, as well as submissions of INDs by Clearside's partners. 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, 2019, filed with the U.S. Securities and Exchange Commission ("SEC") on March 13, 2020, 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.

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