Clearside Biomedical, Inc. Announces First Patient Enrolled in Phase 1/2 Clinical Trial of Zuprata™ in Diabetic Macular Edema

November 15, 2016

ALPHARETTA, Ga., Nov. 15, 2016 (GLOBE NEWSWIRE) -- Clearside Biomedical, Inc. (NASDAQ:CLSD), a late-stage biopharmaceutical company developing first-in-class drug therapies to treat back-of-the-eye diseases, today announced the enrollment of the first patient in a Phase 1/2 clinical trial (the "HULK" trial) of Zuprata™, its proprietary suspension formulation of the corticosteroid triamcinolone acetonide, for the treatment of diabetic macular edema ("DME").

The HULK trial is an open-label, multi-center study designed to assess the safety and efficacy of the administration of Zuprata to the suprachoroidal space ("suprachoroidal Zuprata") concomitant with intravitreal aflibercept, as well as suprachoroidal Zuprata monotherapy, in patients with DME. The trial targets enrollment of approximately 20 patients, with approximately equal numbers in each of the two arms. Anatomical and functional data and safety information will be collected at each monthly visit during the 6-month evaluation period.

"In the Phase 2 TANZANITE trial of suprachoroidal Zuprata concomitant with intravitreal aflibercept in patients with macular edema due to retinal vein occlusion, or RVO, we observed encouraging visual acuity and macular edema improvements," said Clearside's Chief Executive Officer and President, Daniel H. White. "Those data have laid the groundwork for this expansion of the development programs for suprachoroidal Zuprata to include the potential treatment of DME. Importantly, the initiation of the HULK trial marks the fourth indication for Zuprata we have announced to date, and, if successful, could significantly expand the potential patient population for Clearside's suprachoroidal treatments."

About Clearside

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a publicly traded, ophthalmic biopharmaceutical company that envisions a world without blindness. Clearside relentlessly pursues transformative, elegant, precise solutions to restore and preserve vision. Clearside is developing advanced clinical and pre-clinical candidates using a proprietary treatment approach offering unprecedented access to the back of the eye through the suprachoroidal space (SCS™). This offers potentially meaningful treatment benefit to patients suffering from sight threatening diseases like uveitis, RVO, wet AMD and DME. To learn more about how Clearside is changing ophthalmology, please visit us at 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 expectations regarding the clinical development of, and the potential market for, Clearside's product candidates. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the U.S. Securities and Exchange Commission ("SEC") on November 14, 2016 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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