Clearside Biomedical, Inc. Redirects Pre-Clinical AMD Research Resources Toward Ongoing DME Clinical Development Program

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ALPHARETTA, Ga., Feb. 27, 2017 (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 that it has initiated a strategic realignment of its research and development resources from its pre-clinical development program for axitinib for the treatment of wet age-related macular degeneration (“wet AMD”) toward its ongoing clinical development program for the treatment of diabetic macular edema (“DME”) assessing Zuprata™, its proprietary suspension formulation of the corticosteroid triamcinolone acetonide.

In mid-2016, Clearside announced that it had selected axitinib as the lead compound for the treatment of wet AMD through suprachoroidal administration due to its potency in targeting the VEGF and PDGF receptors, and because of its long half-life when administered suprachoroidally.

However, recent trial results from other industry participants that are pursuing combination therapy agents for wet AMD have led Clearside to reconsider the viability of further development of its proprietary suspension formulation of axitinib. Accordingly, while the Company plans to continue to investigate axitinib and other compounds for the treatment of wet AMD, it no longer expects to submit an Investigational New Drug application to the U.S. Food and Drug Administration for axitinib. Instead, Clearside will shift research and development resources away from wet AMD towards its more advanced DME program.

“Clearside is fortunate to have built a well-diversified pipeline targeting the restoration and preservation of vision,” said Daniel H. White, Clearside’s Chief Executive Officer and President. “Historically, corticosteroids have shown promise in the treatment of DME, but the results have been confounded by side effects like cataracts and elevated intraocular pressure. We believe that the encouraging results that we have observed in our RVO and Uveitis programs suggest that suprachoroidally injected Zuprata may exhibit similar benefits in treating DME. Clearside will, however, continue to explore potential opportunities for the use of suprachoroidal delivery in the wet AMD space.”

In November 2016, Clearside announced the enrollment of the first patient in a Phase 1/2 clinical trial (“HULK”) assessing the administration of Zuprata, either alone or together with EYLEA® (aflibercept), for the treatment of DME. Suprachoroidally injected Zuprata for the treatment of DME is part of Clearside’s pipeline of drug treatments for unmet or underserved blinding eye diseases where the pathologies manifest in the choroid or retina.

About Clearside

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a late-stage ophthalmic biopharmaceutical company that envisions a world without blindness. Clearside relentlessly pursues transformative, elegant, precise solutions to restore and preserve vision. Clearside is developing therapies for eye diseases using a proprietary treatment approach offering high access for the pharmacological candidates to the back of the eye through suprachoroidal injection. This new treatment paradigm offers potentially meaningful therapeutic benefit to patients suffering from sight threatening diseases like uveitis, RVO and DME. To learn more about how Clearside seeks to change ophthalmology treatment, 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 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 reports filed with the SEC from time to time. 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.