# Cue Biopharma Announces Initiation of Investigator Sponsored Trial of CUE-102 in Recurrent Glioblastoma Multiforme

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- *First patient dosed with CUE-102 for recurrent glioblastoma multiforme (rGBM) at Dana-Farber Cancer Institute (DFCI)*

BOSTON, Aug. 13, 2025 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of therapeutic biologics to selectively engage and modulate disease-specific T cells for the treatment of autoimmune disease and cancer, announced today the initiation of an investigator sponsored trial (IST) in rGBM at the DFCI with the first patient in the trial having been dosed with CUE-102. The trial (NCT06917885) is a Phase 1b, open-label study of adjuvant CUE-102, the Company's drug product candidate targeting Wilms' Tumor 1 protein (WT1) expressing cancers. The principal investigator of the Phase 1b trial, David A. Reardon, MD, is the Clinical Director of the Center for Neuro-Oncology at DFCI and a leader in the field of immunotherapy for the treatment of brain cancer. The goal of the study is to evaluate the tolerability and clinical activity of CUE-102 in patients with GBM at first recurrence.

"Glioblastoma remains one of the most aggressive and hard-to-treat cancers, and as a result, there is a pressing need for more effective therapies. Investigational treatments targeting WT1 in GBM have shown a potential correlation between expansion of antigen-specific T cells and survival," said Dr. Reardon. "CUE-102 is designed to target tumor cells by activating WT1 specific T cells, which may improve clinical outcomes in recurrent GBM."

Matteo Levisetti, MD, chief medical officer at Cue Biopharma, added, "Glioblastoma is an immunologically 'cold' tumor representing a disadvantage for treatment with standard immunotherapies such as checkpoint inhibitors, but is known to express high levels of the Wilms' Tumor 1 oncofetal protein. We believe the mechanism of action of CUE-102, to preferentially activate and expand WT1 tumor-specific T cells, has the potential to activate and generate an enhanced anti-tumor immune response against glioblastoma. We are highly encouraged by the clinical data generated to date from the CUE-100 series, CUE-101 and CUE-102, and look forward to reporting results from this investigator sponsored trial."

**About CUE-102**
CUE-102 is Cue Biopharma's second clinical drug candidate from the CUE-100 series of interleukin 2 (IL-2)-based biologics. It is designed to activate and expand Wilms' Tumor 1 (WT1)-specific T cells by presenting the WT1 peptide to the WT1-specific T cell receptor. WT1 is a well-recognized onco-fetal protein known to be over-expressed in a number of cancers, including solid tumors and hematologic malignancies. CUE-102 has demonstrated anti-tumor activity and a favorable tolerability profile with no dose limited toxicities observed in a Phase 1 open label, dose escalation and expansion trial (NCT05360680), for patients with late-stage colorectal, gastric/gastroesophageal junction, pancreatic and ovarian cancers that express WT1.

**About Glioblastoma**
Glioblastomas are the most common primary cancer of the brain and the most aggressive type of brain tumor. There are ~13,000 new cases diagnosed each year in the United States. The most common length of survival following diagnosis is ~12 to 15 months, with fewer than ~3 to 5 percent of people surviving longer than five years.

**About the CUE-100 Series**
The CUE-100 series consists of Fc-fusion biologics that present two signals to T cells. Signal #1 is a tumor-specific peptide linked to a major histocompatibility complex (pMHC) to enable selectivity and specificity. Signal #2 is a rationally engineered interleukin 2 (IL-2) molecule to trigger T cell activation. These singular biologics are anticipated to selectively target, activate and expand a robust repertoire of tumor-specific T cells directly in the patient's body. The binding affinity of IL-2 for its receptor has been deliberately attenuated to achieve preferential selective activation of tumor-specific effector T cells while reducing the potential for effects on regulatory T cells (Tregs) or broad systemic activation, potentially mitigating the dose-limiting toxicities associated with current IL-2-based therapies.

**About Cue Biopharma**
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body. The company's proprietary platform, Immuno-STAT® *(Selective Targeting and Alteration of T cells)*, and biologics are designed to harness the curative potential of the body's intrinsic immune system without the adverse effects of broad systemic immune modulation.

Headquartered in Boston, Massachusetts, we are led by an experienced management team with deep expertise in immunology and immuno-oncology as well as the design and clinical development of protein biologics.

For more information please visit www.cuebiopharma.com and follow us on X and LinkedIn.

**Forward-Looking Statements**
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, those regarding: the company's belief regarding the potential benefits and applications of its drug candidates and programs, including CUE-102's ability to potentially improve clinical outcomes in recurrent GBM and the potential of the Immuno-STAT platform to treat a variety of cancers; and the company's business strategies, plans and prospects. Forward-looking statements, which are based on certain assumptions and describe the company's future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely," "promise" or other comparable terms, although not all forward-looking statements contain these identifying words. All statements other than statements of historical facts included in this press release regarding the company's strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Important factors that could cause the company's actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the company's ability to shift its focus to its autoimmune assets and achieve the cost savings that it is projecting; the company's limited operating history, limited cash and a history of losses; the company's ability to achieve profitability; potential setbacks in the company's research and development efforts including negative or inconclusive results from its preclinical studies or clinical trials or the company's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; serious and unexpected drug-related side effects or other safety issues experienced by participants in clinical trials; its ability to secure required U.S. Food and Drug Administration ("FDA") or other governmental approvals for its product candidates and the breadth of any approved indication; adverse effects caused by public health pandemics, including possible effects on the company's operations and clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; the company's reliance on licensors, collaborators, contract research organizations, suppliers and other business partners; the company's ability to obtain adequate financing to fund its business operations in the future and ability to continue as a going concern; the company's ability to maintain and enforce necessary patent and other intellectual property protection; competitive factors; general economic and market conditions and the other risks and uncertainties described in the Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations sections of the company's most recently filed Annual Report on Form 10-K and any subsequently filed Quarterly Report(s) on Form 10-Q. Any forward-looking statement made by the company in this press release is based only on information currently available to the company and speaks only as of the date on which it is made. The company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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