Cue Biopharma Announces First Patient Dosed in Part B Patient Expansion of CUE-101 Phase 1 Monotherapy Trial in HPV+ Second Line and Beyond HNSCC

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CAMBRIDGE, Mass., June 10, 2021 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics designed to selectively engage and modulate targeted T cells directly within the patient's body, announced today that it has dosed the first patient in the Part B expansion phase of its Phase 1 monotherapy clinical trial of CUE-101 at the recommended Phase 2 dose of 4mg/kg.

The Phase 1b portion of the CUE-101 monotherapy clinical trial in patients with HPV+ second line and beyond (2L+) head and neck squamous cell carcinoma (HNSCC) is expected to enroll up to 20 patients. The data supporting the patient expansion has been encouraging to date, with six patients having confirmed stable disease (SD) and one patient with a confirmed partial response of approximately 50% tumor reduction in the dose escalation Phase 1a portion of the CUE-101 monotherapy trial.

"We are very pleased to have initiated the Part B patient expansion of the CUE-101 monotherapy trial," stated Ken Pienta, M.D., acting chief medical officer of Cue Biopharma. "We believe the data supporting the selection of the cohort 6 dose at 4mg/kg to confirm a recommended Phase 2 dose gives us growing confidence that CUE-101 may provide a potential path forward for a registration-directed clinical trial as a single agent treatment for HPV+ 2L+ HNSCC."

About the CUE-101 Clinical Trial
The trial (NCT03978689) is a multi-center, first-in-human, open-label Phase 1 dose escalation and expansion study evaluating the safety, anti-tumor effect and immunogenicity of CUE-101 as a monotherapy in second-line patients with confirmed HPV16-driven recurrent/metastatic HNSCC and HLA-A*02:01 serotype. Based on translational data from the Phase 1a portion of the trial, a recommended Phase 2 dose has been determined. The company has expanded the study to evaluate CUE-101 in combination with KEYTRUDA® (pembrolizumab) as first-line treatment in patients with HPV16-driven recurrent/metastatic HNSCC.

About the CUE-100 Series
The CUE-100 series consists of Fc-fusion biologics that incorporate peptide-MHC (pMHC) molecules along with rationally engineered IL-2 molecules. This singular biologic is anticipated to selectively target, activate and expand a robust repertoire of tumor-specific T cells directly in the patient. 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 Immuno-STAT
The company's Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* biologics are designed for targeted modulation of disease-associated T cells in the areas of immuno-oncology and autoimmune disease. Each of our biologic drugs is designed using our proprietary scaffold comprising: 1) a pMHC to provide selectivity through interaction with the T cell receptor (TCR), and 2) a unique co-stimulatory signaling molecule to modulate the activity of the target T cells.

The simultaneous engagement of co-regulatory molecules and pMHC binding mimics the signals delivered by antigen presenting cells (APCs) to T cells during a natural immune response. This design enables Immuno-STAT biologics to engage with the T cell population of interest, resulting in selective T cell modulation. Because our drug candidates are delivered directly in the patient's body (in vivo), they are fundamentally different from other T cell therapeutic approaches that require the patients' T cells to be extracted, modified outside the body (ex vivo), and reinfused.

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells directly within the patient's body to transform the treatment of cancer, infectious disease and autoimmune disease. The company's proprietary Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* platform, is designed to harness the body's intrinsic immune system without the need for ex vivo manipulation.

Headquartered in Cambridge, Massachusetts, the company is led by an experienced management team and independent Board of Directors with deep expertise in immunology and immuno-oncology as well as the design and clinical development of protein biologics.

For more information, visit https://www.cuebiopharma.com and follow us on Twitter at https://twitter.com/CueBiopharma.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as

amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the safe harbor created by those sections. Such forward-looking statements include, but are not limited to, those regarding: the expected patient enrollment in the Phase 1b portion of the CUE-101 monotherapy clinical trial; the potential for CUE-101 to treat HPV+ 2L+ HNSCC; 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" 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 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, 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 COVID-19, including possible effects on the company's operations and clinical trials; negative or inconclusive results from the company's clinical trials or preclinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in 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; 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 in 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 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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