Cue Biopharma Initiates Patient Dosing in Phase 1 Study of CUE-101 in Combination with KEYTRUDA® (pembrolizumab) as First-line Treatment for HPV+ Recurrent/Metastatic Head and Neck Cancer

February 8, 2021

CAMBRIDGE, Mass., Feb. 08, 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 within the patient's body, announced today that on February 1, 2021, the first patient was dosed in a Phase 1 dose escalation clinical trial of CUE-101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA ® (pembrolizumab). CUE-101 is being evaluated in combination with KEYTRUDA® as first-line treatment for human papilloma virus positive recurrent/metastatic head and neck squamous cell carcinoma (HPV+ R/M HNSCC).

"We are very pleased to have initiated our combination trial of CUE-101 with KEYTRUDA," said Ken Pienta, M.D, acting chief medical officer of Cue Biopharma. "In our ongoing dose escalation monotherapy Phase 1 trial, CUE-101 has been well tolerated at doses where we've observed preliminary evidence of clinical activity, and in preclinical studies we've demonstrated that the combination of CUE-101 and checkpoint blockade appear synergistic by significantly extending survival in mouse models of HPV positive cancers. These data taken together support our belief that the combination of CUE-101 with KEYTRUDA has the potential to enhance anti-tumor activity and prolong patient survival."

This Phase 1 dose escalation combination trial (NCT03978689) is being conducted in parallel at the same clinics that are conducting the ongoing Phase 1 monotherapy study of CUE-101. Due to the tolerability profile demonstrated to date in the CUE-101 monotherapy dose escalation trial, the first dose in the combination arm is 1 mg/kg every three weeks (Q3W), which is also the recommended dosing interval for KEYTRUDA.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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 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 highly targeted 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 within the patient's body to transform the treatment of cancer, infectious diseases and autoimmune diseases. The company's proprietary platform, Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* is designed to harness the body's intrinsic immune system without the need for ex vivo manipulation.

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

For more information, visit www.cuebiopharma.com and follow us on Twitter 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 potential of the CUE 100 series for anti-tumor activity; the potential benefits of the company's Immuno-STAT™ platform biologics; the anticipated results of the company's drug development efforts, including study results; the company's expectations regarding regulatory developments and expected future operating results; and statements regarding the company's strategies, prospects, financial condition, operations, costs, plans and objectives. 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. 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 history of losses; the company's ability to achieve profitability; potential setbacks in the company's research and development efforts 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.

Investor Contact
George B. Zavoico, Ph.D.
VP, Investor Relations & Corporate Development
Cue Biopharma, Inc.
gzavoico@cuebio.com

Media Contact
Karen O'Shea, Ph.D.
LifeSci Communications
koshea@lifescicomms.com

Source: Cue Biopharma, Inc.