Cue Biopharma Announces Publication in The Journal of Clinical Investigation Highlighting Immuno-STAT Biologics for the Treatment of Chronic Infectious Diseases

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Research demonstrates Immuno-STAT™ Biologics lead to direct and selective activation and expansion of anti-viral cytotoxic T cells in vivo specific for human immunodeficiency virus (HIV) and cytomegalovirus (CMV) highlighting potential as immunotherapeutics for a variety of chronic infectious diseases

CAMBRIDGE, Mass., Oct. 21, 2021 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells directly within the patient's body, announced today the publication of a research study titled "*T-Cell Receptor-specific Immunotherapeutics Drive Selective In vivo HIV and CMV- specific T-Cell Expansion in Humanized Mice*" in the peer-reviewed *Journal of Clinical Investigation.* The article extends the application of Cue Biopharma's Immuno-STAT *(Selective Targeting and Alteration of T cells)* platform, also known as synTacs™, from cancer therapy to the treatment of chronic infectious diseases caused by viruses such as HIV and CMV. The study was co-authored by Steven C. Almo, Ph.D., co-founder of Cue Biopharma, professor and chair of biochemistry, professor of physiology & biophysics and the Wollowick Family Foundation chair in multiple sclerosis and immunology at Albert Einstein College of Medicine, and Harris Goldstein, M.D., director of the Einstein-Rockefeller-CUNY Center for AIDS Research, professor of pediatrics and microbiology & immunology, the Charles Michael chair in autoimmune diseases and associate dean for scientific resources, also at Albert Einstein College of Medicine.

"We hypothesized that we could boost the capacity of the natural immune response to effectively control and potentially clear chronic viral infections such as HIV and CMV by treating patients with biologics capable of selectively delivering the required primary and co-stimulatory signals needed to further activate and expand virus-specific immune T cells. Therapeutic approaches to date have not achieved this without *ex vivo* manipulation of immune T cells, which limits their clinical applicability," said Dr. Goldstein. "We are pleased to demonstrate, using mice with a humanized immune system, the successful *in vivo* application of the Immuno-STAT framework, referred to as synTacs in the article, to selectively reactivate and expand virus-specific human immune T cells and suppress HIV and CMV infection. This supports the potential use of the Immuno-STAT framework to treat infectious diseases by directly amplifying virus-specific immune responses within the patient's body. The objective of this research is to boost the cytotoxic activity of HIV-specific CD8+ T cells, thereby increasing their capacity to eliminate HIV-infected cells with the aim of achieving a functional cure for HIV-1 infection."

Dr. Almo added, "This research demonstrates how Immuno-STATs, or "synTacs", are able to activate HIV-specific cytotoxic T cells *in vivo*. This is a significant accomplishment considering that a major barrier in preventing a functional cure for HIV-infected individuals is the inability of their natural anti-HIV-specific cytotoxic T cells to eliminate infected cells after standard of care antiretroviral therapy ends. Given the modularity of this platform, which enables swapping of the costimulatory signals and the antigen-specific signals to any viral molecule, these data serve as proof-of-concept to not only demonstrate the potential of synTacs to treat HIV, but a variety of other infectious diseases, including novel viral infections such as SARS-Cov-2."

Anish Suri, Ph.D., president and chief scientific officer of Cue Biopharma, added, "The clinical potential of Immuno-STAT biologics is already being revealed in our ongoing Phase 1 clinical trial of CUE-101, our lead drug product candidate, in head and neck squamous cell carcinoma (HNSCC), which has shown a positive safety and efficacy profile to date. We are highly encouraged by these key datasets published by Dr. Steven Almo and Dr. Harris Goldstein, which demonstrate the potential of our biologics platforms to selectively activate virus-specific T cells for therapeutic applications across chronic infectious diseases, transplant rejection, graft-versus-host-disease (GVHD) and enhancing anti-tumor immunity."

Albert Einstein College of Medicine and its faculty members acknowledge the following relationships with Cue Biopharma, Inc.: Dr. Almo holds equity in Cue Biopharma, Inc., receives royalties from existing license agreements between Einstein and Cue Biopharma, and is a member of its Science Advisory Board. Albert Einstein College of Medicine holds equity in Cue Biopharma and receives royalties from existing licensing agreements. Dr. Almo and Dr. Goldstein have received prior funding from Cue Biopharma under a sponsored research agreement.

About the CUE-200 Series

The Immuno-STAT platform enables development of first-in-class off-the-shelf biologic molecules designed to selectively engage and activate disease-relevant T cells via the T cell receptors (TCR), mimicking the natural immune process, through the presentation of complimentary and synergistic signals, or "cues." The Immuno- STAT CUE-200 series is engineered to include: 1) a first signal or "cue" involving the presentation of a specific disease protein, via a major histocompatibility (MHC)-peptide complex, to T cell receptors (TCRs) of disease-specific T cells, and 2) a second costimulatory ligand receptor such as CD28- or 4-1BB, able to promote activation and expansion of CD8+ cytotoxic T cells, the relevant type of T cells with virus-killing activity. The Immuno-STAT is constructed upon a portion of a human antibody (the "Fc portion") that serves as the molecule's backbone or scaffold and provides manufacturability and structural stability.

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.

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 company's estimate of the period in which it expects to have cash to fund its operations; the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells; 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 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; operations and clinical 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 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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