Cue Biopharma Announces Nature Methods Publication of Preclinical Data Showing Tumor Penetration and Antigen-Specific T Cell Engagement with Immuno-STAT Based Protein Scaffolds

September 15, 2020

Novel positron emission tomography approach demonstrates the ability of Immuno-STAT based scaffolds to selectively engage tissue-resident T cells including intratumoral T cells of defined specificity

CAMBRIDGE, Mass., Sept. 15, 2020 (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 within the body, announced today the peer-reviewed publication of preclinical data focused on the in vivo detection of tumor antigen-specific T cells in a paper published in *Nature Methods* titled, "*In vivo detection of antigen-specific CD8 T cells by immuno-positron emission tomography*." 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 Hidde Ploegh, Ph.D., a renowned expert in molecular immunology and a member of the program in cellular and molecular medicine at Boston Children's Hospital.

In this work, researchers employed dimeric protein scaffolds to develop a novel immuno-positron emission tomography (immunoPET) imaging approach. These protein scaffolds, known as synTacs, consist of Fc-based covalent peptide-major histocompatibility complex (pMHC) dimers, which form the core structure of Cue Biopharma's Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* platform. By targeting synTacs labelled with positron emitting isotopes against specified tumor antigens, researchers were able to specifically and non-invasively detect tumor antigen-specific T cells in murine solid tumor models. In the same study, similar application of synTacs deploying viral antigens could detect and engage virus-specific T cells in the lung tissue.

"These studies demonstrate the remarkable breadth of applications supported by the Immuno-STAT platform, as it enables clinical applications for highly selective targeted treatments of cancer, autoimmune diseases and infectious diseases, but, also as demonstrated in the *Nature Methods* paper, the potential to serve as prognostics and diagnostics for mechanism-of-action and treatment efficacy by revealing the in vivo distribution of the biologic and its target T cells in diseased tissue," said Dr. Almo.

"This work highlights the power of the Sortase A coupling technology developed in our lab, as it readily allowed the site-specific, stoichiometric and highly reproducible installation of PET imaging tags ($^{64}Cu^{2+}$ and $^{89}Zr^{4+}$ and ^{18}F) for the in vivo tracking of antigen-specific T cells targeting tumor cells and virally infected cells in the disease tissue. These advances highlight the strength of modular biologic platforms, like the Immuno-STAT platform, that can be deployed for targeting and tracking antigen-specific effector lymphocytes in the patients to gain predictive insights into pharmacodynamic and clinical responses," elaborated Dr. Ploegh.

Specific detection of intratumoral T cells by this newly developed immunoPET approach provides further support that the core component of the Immuno-STAT scaffold can penetrate into the tumors and directly engage tumor-resident T cells. These data highlight the modular nature and the broad applicability of the Immuno-STAT platform to selectively deliver cargoes, such as imaging agents or immunomodulatory signals to tumor-resident T cells.

Anish Suri, Ph.D., president and chief scientific officer of Cue Biopharma, commented, "We are highly encouraged by these results, as they highlight the inherent advantages of our engineered biologics platforms. Data showing the efficient penetration of the HPV16 E7 targeted synTac into solid tumors are particularly noteworthy, as similar technologies are unable to deliver cargoes past the tumor periphery. Further, this synTac is analogous to our lead asset, CUE-101, which carries a covalently linked IL-2 variant and is currently being evaluated in a Phase 1 trial in HPV16 driven head and neck squamous cell carcinoma."

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, and is a member of its Science Advisory Board. Albert Einstein College of Medicine holds equity in Cue and receives royalties from existing licensing agreements.

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 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.

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. Forward-looking statements, which are based on certain assumptions and describe our 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. All statements other than statements of historical facts included in this press release regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements.

Examples of forward-looking statements include, among others, statements we make regarding anticipated results of our drug development efforts, including study results, and our expectations regarding regulatory developments and expected future operating results. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, our limited operating history, limited cash and a history of losses; our ability to achieve profitability; potential setbacks in our research and development efforts including negative or inconclusive results from our preclinical studies, our ability to secure required U.S. Food and Drug Administration ("FDA") or other governmental approvals for our product candidates and the breadth of any approved indication; adverse effects caused by public health pandemics, including COVID-19, including possible effects on our operations and clinical trials; negative or inconclusive results from our clinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in our clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; our reliance on licensors, collaborators, contract research organizations, suppliers and other business partners; our ability to obtain adequate financing to fund our business operations in the future; 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 our 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 us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake 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.

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

Media Contact
Alison Chen
LifeSci Communications
achen@lifescicomms.com

Source: Cue Biopharma, Inc.