Cue Biopharma Announces Publication in Clinical Cancer Research of Preclinical and Translational Data Supporting the Therapeutic Potential of CUE-101 in HPV16-Related Malignancies

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CAMBRIDGE, Mass., Jan. 21, 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 publication of research demonstrating the ability of its lead biologic candidate CUE-101 to activate tumor antigen specific antitumor immunity in the peer-reviewed medical journal *Clinical Cancer Research,* a journal of the American Association for Cancer Research. The manuscript by Steven Quayle et al. is titled "*CUE-101, a Novel HPV16 E7 pHLA-IL-2-Fc Fusion Protein, Enhances Tumor Antigen Specific T Cell Activation for the Treatment of HPV16-Driven Malignancies."* (http://bit.ly/2twfkxd)

The research highlights the ability of the company's proprietary Immuno-STAT™ (*Selective Targeting and Alternation of T cells*) platform to selectively engage and modulate targeted T cells within the body. CUE-101 is the company's lead drug candidate from the IL-2 based CUE-100 series designed to directly engage and activate T cells to target HPV16-driven recurrent/metastatic head and neck squamous cell carcinoma (HNSCC).

The published results show that CUE-101 demonstrated selective binding, activation and expansion of the disease-relevant human T cell population in vitro, as well as predict a favorable safety profile. A murine surrogate molecule (mCUE-101) administered to HPV16 E7 tumor bearing mice resulted in selective expansion of disease-relevant T cells, anti-cancer efficacy and immunologic memory. In addition, mCUE-101 administered as a combination therapy with anti-PD-1 checkpoint inhibition further enhanced anti-tumor efficacy. These data support the potential for CUE-101 to enhance anti-tumor immunity in HPV16-driven malignancies. CUE-101 is currently being studied in a Phase 1 clinical trial (NCT03978689) for HPV16-driven HNSCC. The Phase 1 trial is evaluating the safety and tolerability, anti-tumor response, pharmacokinetics and immunogenicity of CUE-101 as a monotherapy in patients with confirmed HPV16-driven recurrent/metastatic HNSCC and HLA-A*02:01 serotype. Based on results from this trial, including translational pharmacodynamic immunoprofiling data, the company may expand the study to test CUE-101 in the neoadjuvant setting and in combination with checkpoint inhibitors in patients with HPV16-driven HNSCC.

"This seminal publication from Cue Biopharma exemplifies the core-strength of our Immuno-STAT biologics platform, in particular the CUE-100 series that incorporates rationally engineered IL-2 molecules for selective activation of tumor-specific T cells. The preclinical and ex vivo human translational data presented in this paper underscore the promising potential for the current, ongoing clinical study evaluating CUE-101 monotherapy in HPV-driven head and neck cancer," stated Anish Suri, Ph.D., president and chief scientific officer of Cue Biopharma.

HPV-driven cancers account for more than 20,000 deaths each year in the U.S. and Europe. The majority of these cancers are driven by HPV16 which carries the E7 protein targeted by CUE-101. Despite treatment with current standards of care, approximately 50% of patients with advanced disease will experience recurrence and significant quality of life impact. Patients with HPV-driven cancers represent an important unmet clinical need and underscore the opportunity for promising new therapeutics.

Clinical Cancer Research is a peer-reviewed medical journal published by the American Association for Cancer Research (AACR). The journal publishes innovative clinical and translational cancer research studies that bridge the laboratory and the clinic.

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
Immuno-STAT™ 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 peptide-MHC complex (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-stimulatory 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 drugs 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, stimulated and expanded outside the body (ex vivo), and reinfused in an activated state.

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 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, MA, 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.cuebio.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, 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; 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; 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, collaborations and strategic alliances; 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.

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