Cue Biopharma Presents Foundational Data on Immuno-STAT Platform and CUE-101 at the Society for Immunotherapy of Cancer's (SITC) 33rd Annual Meeting

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CUE-101 Demonstrates Selective Binding and Preferential Activation/Expansion of Antigen-specific T Cells, Inhibition of Tumor Growth as Monotherapy and in Combination with a PD-1 Inhibitor

CAMBRIDGE, Mass., Nov. 09, 2018 (GLOBE NEWSWIRE) -- Cue Biopharma ™, Inc., (NASDAQ: CUE) an innovative immunotherapy company developing a novel, proprietary class of biologics engineered to modulate antigen-specific T cells to treat cancer, autoimmune and chronic infectious diseases, announced today preclinical results demonstrating the potential of its Immuno-STAT™ (Selective Targeting and Alteration of T cells) platform and lead candidate CUE-101. In the study, CUE-101 demonstrated selective binding and preferential activation and expansion of antigen-specific T cells, dose-dependent effector cytokine production and inhibition of tumor growth both as a monotherapy and in combination with a PD-1 inhibitor. The poster, entitled "CUE-101, a novel Fc fusion protein comprised of HLA-A*0201-bound HPV16 E7 peptide and IL-2, for selective targeting and expansion of anti-tumor T cells for treatment of HPV-driven malignancies," (P185) is being presented today during the poster session at the Society for Immunotherapy of Cancer's (SITC) 33rd Annual Meeting being held in Washington, D.C.

"This study highlights the unique qualities and potential of our Immuno-STAT platform to selectively activate antigen-specific T cells to generate robust targeted immune responses in one of our areas of focus, oncology," said Anish Suri, Ph.D., Senior Vice President and Chief Scientific Officer of Cue Biopharma. "CUE-101 demonstrated several key features in this study including selective targeting of antigen-specific T cells and preferential proliferation and expansion of those T cells both in vivo and in human peripheral blood mononuclear cells. We also showed in preclinical models that a murine surrogate, designated mCUE-101, inhibits tumor growth both as a monotherapy, and demonstrating significant synergy when combined with a PD-1 inhibitor."

Cue Biopharma's data underscores the potential of the ImmunoSTAT platform for selectively targeting and expanding T cells via a peptide-MHC complex (pMHC), and induces dose-dependent effector cytokine production, including secretion of IFNγ, from antigen-specific CD8+ T cells.

The data shows, in a preclinical tumor model, that mCUE-101 inhibited tumor growth both as a monotherapy and in combination with a PD-1 inhibitor. mCUE-101 alone significantly extended overall survival in this model, which was further improved when mCUE-101 was combined with a PD-1 inhibitor. Importantly, PD-1 alone, in this model, showed no extended overall survival benefit. Furthermore, when tumors were re-introduced in long-term protected mice, significant tumor rejection was evident in absence of any additional treatments, demonstrating functional immunologic memory. In the same disease model, mCUE-101 demonstrated selective expansion of E7-specific T cells in the blood and tumor. Notably, tumor-specific T cells in the tumor expressed PD-1, which provided a mechanistic explanation for enhanced efficacy when mCUE-101 was combined with a PD-1 inhibitor.

The poster will be available in the Events and Presentations section of the Investor page at www.cuebio.com following the presentation at SITC's 33rd Annual Meeting.

CUE-100 Framework
Candidates developed within our CUE-100 framework (pMHC/affinity-attenuated IL-2) selectively stimulate the interleukin 2 (IL-2) receptor, a potent T cell activation pathway critical to the growth, expansion and survival of T cells. Cue has engineered the IL-2 signal to specifically activate targeted T cells populations. By deploying IL-2 to disease-associated T cell subsets preferentially through pMHC targeting, our biologics aim to achieve enhanced efficacy while significantly mitigating the dose-limiting toxicities associated with current therapies.

Our lead compound from the CUE-100 framework, CUE-101, is a fusion of a variant form of the cytokine Interleukin-2 ("IL-2") and a peptide-MHC complex (pMHC) derived from the human papilloma virus E7 protein (HPV-E7). It is a single, covalently-assembled biologic designed to target and activate antigen-specific T cells to fight HPV-driven cancers.

About Cue Biopharma
Cue Biopharma is an innovative immunotherapy company developing a novel, proprietary class of biologics engineered to selectively modulate the human immune system to treat a broad range of cancers, autoimmune and chronic infectious diseases. We design biologics to engage and modulate the activity of disease-associated T cells in the patient's body, with the goal of offering significant therapeutic benefits while potentially minimizing or eliminating unwanted side effects.

We believe our selective biologics allow us to target antigen-specific T cell populations in a variety of indications using a peptide – MHC complex for delivering T cell modulating effectors, such as IL-2. Once a biologic has been optimized, our approach offers the potential for readily exchanging peptides to target different T cell populations and indications using previously-validated drug frameworks developed from the Immuno-STAT™ (Selective Targeting and Alteration of T cells) platform. This flexibility could truncate the drug selection and development process, moving effective therapeutics from discovery to clinical validation more rapidly and cost-efficiently than current industry standard timelines and costs.

Headquartered in Cambridge, MA, we are led by an experienced management team and scientific and clinical advisory board (SAB/CAB) with deep expertise in the design and clinical development of protein biologics, immunology and immuno-oncology.

For more information, visit www.cuebio.com.

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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