Cue Biopharma Announces Presentations Highlighting Clinical Progress of CUE-101, Pipeline Progress of CUE-100 Series Immuno-STATs and Immuno-STAT Data for Infectious Disease Applications at the Society for Immunotherapy of Cancer's (SITC) 35th Anniversary

November 9, 2020

CAMBRIDGE, Mass., Nov. 09, 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 patient's body, announced today three poster presentations highlighting the Company's clinical and pipeline progress at the Society for Immunotherapy of Cancer's 35th Anniversary Annual Meeting (SITC 2020). The posters include a clinical update on CUE-101, the lead drug candidate from the IL-2 based CUE-100 series, and data supporting the potential of the Immuno-STAT ™*(Selective Targeting and Alteration of T cells)* platform to selectively engage and modulate targeted T cells within the body in a manner that can address a broad range of indications.

"We are pleased to share data providing further supportive evidence of the potential benefits of our Immuno-STAT platform throughout its stages of development," said Anish Suri, Ph.D., president and chief scientific officer of Cue Biopharma. "We are encouraged by the dose-proportional signals and metrics of clinical activity as well as the tolerability observed in our ongoing Phase 1 trial of CUE-101, as we continue enrollment with the next incremental level of dosing. Our preclinical data demonstrate the potential versatility and modularity of the Immuno-STAT platform for a wide array of indications, including the potential for prognostics and diagnostics, with evidence of localization and engagement with disease-relevant T cells, as well as activation and expansion."

Due to the abstract submission and acceptance dates for SITC, the poster highlighting progress on CUE-101 will only contain data updates through cohort 4. Members of the Cue Biopharma executive management team will provide further updates and details pertaining to patients from cohorts 4, 5 and 6 at the upcoming quarterly update call on November 17 at 4:30 p.m. EST. In addition, Cue Biopharma has recently received permission from the Clinical Safety and Review Committee to proceed with dose escalation to cohort 7 at 8 mg/kg.

The SITC Presentations include:

A phase 1 trial of CUE-101 a novel HPV16 E7-pHLA-IL2-Fc fusion protein in patients with recurrent/metastatic HPV16+ head and neck cancer (Abstract #354)
Presenter: Sara I. Pai, M.D., Ph.D., associate professor, Massachusetts General Hospital and Harvard Medical School, Boston

An ongoing multicenter, open-label, dose escalation Phase 1 trial is evaluating the safety, tolerability, anti-tumor response, pharmacokinetics and immunogenicity of CUE-101 as a monotherapy in patients with confirmed human papilloma virus positive recurrent/metastatic head and neck squamous cell carcinoma (HPV+ HNSCC) and HLA-A*02:01 serotype (NCT03978689). Results from 19 participants who have received CUE-101 at doses ranging from 0.06 to 1 mg/kg demonstrate acceptable tolerability, favorable pharmacokinetics (PK) and preliminary pharmacodynamics (PD) signals that indicate selective activation of tumor-specific T cells, enabling dose escalation to the next level (2 mg/kg).

CUE-100 series Immuno-STATs from concept to the clinic: Leveraging protein engineering to stimulate and selectively deliver affinity-attenuated IL-2 to antigen-specific T cells (Abstract #553)
Presenter: Saso Cemerski, Ph.D., vice president and head, discovery and translational immunology, Cue Biopharma

In vitro and *in vivo* evaluation of CUE-100 series Immuno-STATs specific to different antigenic peptides demonstrated expansion of functional, oligoclonal, antigen-specific T cell repertoires with functional attenuation of the IL-2 components. CUE-100 series Immuno-STATs administered to human peripheral blood mononuclear cells (PBMCs) selectively activated and expanded antigen-specific CD8+ T cells after primary stimulation and re-stimulation with antigenic peptides from HPV16, Wilms' tumor 1 (WT1), melanoma antigen recognized by T cells 1 (MART-1), cytomegalovirus (CMV), influenza and HIV. In naïve HLA-A*02 transgenic mice, CUE-100 series Immuno-STATs expanded CD8+ T cells, exhibiting a polyfunctional response upon challenge with peptide-presenting target cells.

Immuno-STATs: Leveraging protein engineering to expand and track antigen-specific T cells in vivo (Abstract #623)
Presenter: Steven Almo, Ph.D., co-founder, Cue Biopharma

The potential modularity of the Immuno-STAT platform and ability to selectively deliver costimulatory, coinhibitory or cytokine signals and other modalities to primary T cells of defined specificity was observed through the use of a novel immuno-positron emission tomography (PET) imaging approach. PET-active radiolabels were installed on dimeric protein scaffolds comprising the core structure of the Immuno-STAT to visualize the *in vivo* localization of antigen-specific T cells. Results showed that HPV16-specific CD8+ T cells were localized to implanted HPV16-positive tumors in mice, and influenza A virus (IAV)-specific CD8+ T cells were localized to the lungs of IAV-infected mice. HIV- and CMV-specific Immuno-STATs administered to immunodeficient mice intrasplenically engrafted with human PBMCs resulted in selective expansion of disease-relevant T cells in the spleen. These data represent the first report of the *in vivo* imaging of antigen-specific CD8+ T cell populations and *in vivo* antigen-selective expansion of human CD8+ T cells, which suggests the presence of Immuno-STAT biologics in the particular tumor or infected tissues where they act, eliciting selective activation and expansion of target T cells. These results suggest that, in addition to broad therapeutic applications, Immuno-STATs may also provide prognostic and diagnostic information.

For more information on all three posters please visit: https://bit.ly/3k4HymQ.

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-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 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, 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 versatility and modularity of the Immuno-STAT platform for a wide array of indications, including the potential for prognostics and diagnostics; the potential ability of the Immuno-STAT platform to selectively deliver costimulatory, coinhibitory or cytokine signals and other modalities to primary T cells; the ability of CUE-101 to selectively activate tumor-specific T cells; the company's plans to advance CUE-101 and its other Immuno-STATs; the anticipated results of the company's drug development efforts, including study results; and the company's expectations regarding regulatory developments and expected future operating results. 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 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 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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