Cue Biopharma to Present an Updated Overview of Immuno-STAT Platform at the 2022 Festival of Biologics World Immunotherapy Congress

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CAMBRIDGE, Mass., March 02, 2022 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of injectable biologics designed to selectively engage and modulate targeted T cells directly within the patient's body, announced today it will give an oral presentation at the Festival of Biologics World Immunotherapy Congress which is being held at the Marriott Marquis in San Diego, California March 9-11, 2022.

At the conference, Cue Biopharma's senior vice president of clinical development, Dr. Matteo Levisetti, will present an updated overview of Cue Biopharma's Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* platform, designed to enable selective engagement and activation of tumor-specific T cells. Dr. Levisetti will also highlight recent data from the ongoing clinical trial of CUE-101, the Company's lead clinical candidate representative of the interleukin 2 (IL-2)-based CUE-100 series, in patients with human papilloma virus positive recurrent/metastatic head and neck squamous cell carcinoma (HPV+ R/M HNSCC). Data demonstrates favorable tolerability throughout a range of doses and anti-tumor activity as a monotherapy in late stage (HPV+ R/M HNSCC) patients. The data provides support for proof of concept and de-risking of CUE-101 as well as subsequent programs and platform applications across the IL-2 based CUE-100 series. Additionally, Dr. Levisetti will discuss Cue Biopharma's platform expansion via Neo-STAT™ and bispecific RDI-STAT™, which allows for targeting multiple tumor antigens and for harnessing the protective anti-viral T cell repertoire to destroy tumors, respectively.

Presentation Details
Title: Targeting IL-2 to tumor-specific T cells via novel biologic platforms
Presenter: Dr. Matteo Levisetti, senior vice president, clinical development
Date & Time: Thursday, March 10, 2022 at 2:20 p.m. PST or 5:20 p.m. EST

"We are very pleased to have Dr. Levisetti present an updated overview of the IL-2 based CUE-100 series at the 2022 Festival of Biologics, with a particular emphasis on the promising clinical data that provides clear differentiation for our strategy focused on selective activity of IL-2 on tumor-specific T cells," said Dr. Anish Suri, president and chief scientific officer of Cue Biopharma. "IL-2 has been a validated therapeutic target with significant hurdles pertaining to lack of specificity, systemic immune activation and serious toxicities. We believe the preliminary anti-tumor activity and positive tolerability profile of CUE-101 is highly encouraging and supportive of its mechanistic advantages and superior differentiation from all other IL-2 variants in development. CUE-101 has demonstrated an impressive tolerability profile as a monotherapy and has achieved targeted engagement of tumor specific T cells without reaching a maximum tolerated dose (MTD). With its unique mechanism of action, we believe CUE-101 has the potential to change the treatment landscape and improve the lives of patients with head and neck cancer as well as a broad range of other indications."

About the Festival of Biologics
The Festival of Biologics brings together pharma & biotech, academics and research institutes, together with their partners across the value chain. Across antibodies, immunotherapy and biosimilars participants share research, create new partnerships, and tackle the clinical trials, manufacturing and commercial challenges involved in bringing new therapies to market.

About the CUE-100 Series
The CUE-100 series consists of Fc-fusion biologics that incorporate peptide-major histocompatibility complex (pMHC) molecules along with rationally engineered interleukin 2 (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 the 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
The company's Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* 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-major histocompatibility 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 selective T cell modulation. Because our drug candidates 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 disease and autoimmune disease. 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 immunology and immuno-oncology as well as the design and clinical development of protein biologics.

For more information please visit 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 potential for CUE-101 to treat HPV+ R/M HNSCC; the company's plans to select the CUE-101 monotherapy Phase 2 clinical trial dose in mid-2021; the company's plans to report initial Phase 1 results of the CUE-101 +pembrolizumab combination trial in the second half of 2021; anticipated initiation of the CUE-101 Phase 2 clinical trial to evaluate effects of CUE-101 on tumor microenvironment and expand patient access and market potential for CUE-101 in the second half of 2021; the potential of the CUE 100 series for anti-tumor activity; the potential benefits of the company's Immuno-STAT™ platform biologics; the anticipated results of the company's drug development efforts, including study results; the company's expectations regarding regulatory developments and expected future operating results; and statements regarding the company's strategies, prospects, financial condition, operations, costs, plans and objectives. 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. 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 history of losses; the company's ability to achieve profitability; potential setbacks in the company's research and development efforts 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 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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