Cue Biopharma to Present at the Biomarkers Series UK

February 12, 2020

CAMBRIDGE, Mass., Feb. 12, 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 Dr. Mary Simcox, vice president of translational biology and early development, will give a presentation highlighting the strategy and tactical details for testing CUE-101, the company's lead biologic drug candidate, in a first-in-human Phase 1 trial (NCT03978689) at the Biomarkers Series UK taking place on Feb. 18-20, 2020 at the Manchester Central Convention Complex. CUE-101 is designed to directly engage and activate T cells in the body to target HPV16-driven recurrent/metastatic head and neck squamous cell carcinoma (HNSCC), enabled by the company's proprietary therapeutic platform Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)*.

Presentation Details
Title: CUE-101 Phase 1 Trial in HNSCC Patients: Novel Immunotherapy Enabled by Patient Stratification & Pharmacodynamic Biomarkers
Session: Biomarker Congress Workshop, End-user Session, Designing/Applying a Biomarker Plan in Drug Development
Presenter: Mary Simcox, Ph.D., vice president of translational biology and early development
Date & Time: Feb. 18 at 4:15 p.m. GMT

"This presentation focuses on the importance of conducting early clinical immuno-oncology trials that are informed by detailed biomarker analyses, which characterize the mechanism of action and provide guidance on how the drug is used to maximize the potential for clinical benefit in cancer patients," said Ken Pienta, M.D., acting chief medical officer of Cue Biopharma. "The CUE-101 Phase 1 protocol includes implementation of multiple technologies and multiple industry and academic partners in the investigation of pharmacodynamic, response prediction, patient selection and response monitoring biomarkers. These critical biomarker data will be collected with the aim to discover correlative pharmacodynamic and response prediction markers to optimize the probability of clinical success and development of a promising and potentially new and transformative therapeutic."

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 designed 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 Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* platform 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 treatments.

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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