



Cue Biopharma Initiates Patient Dosing in Phase 1 Study of CUE-101 for HPV16-driven Head and Neck Squamous Cell Carcinoma

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CAMBRIDGE, Mass., Sept. 30, 2019 (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 that on September 23, 2019 it dosed the first patient in a Phase 1 clinical trial of CUE-101 at [Washington University, Alvin J. Siteman Cancer Center, St. Louis, Missouri](#) for the treatment of HPV16-driven recurrent/metastatic head and neck squamous cell carcinoma (HNSCC). Enabled by the company's proprietary Immuno-STAT™ (*Selective Targeting and Alternation of T cells*) platform, CUE-101 is the company's lead biologic drug candidate from the IL-2 based CUE-100 series, designed to directly engage and activate T cells in the body to target HPV-driven cancers.

"We are very pleased to have begun dosing patients with CUE-101, the first drug candidate from our CUE-100 series designed by our proprietary Immuno-STAT platform. We believe CUE-101 has the potential to activate the patient's immune system against HPV16-driven cancers by selectively targeting and activating the patient's T cells directly within their body, representing a potential breakthrough approach for harnessing the therapeutic power of the body's immune system," said Dan Passeri, president and chief executive officer of Cue Biopharma.

Ken Pienta, M.D., acting chief medical officer of Cue Biopharma, added, "As an oncologist, I am extremely excited about this promising new approach to treat cancer by stimulating a patient's own immune system. We are thrilled to enroll patients suffering from refractory HPV16 positive head and neck cancer."

"Initiating this Phase 1 clinical study of CUE-101 is a significant milestone for Cue Biopharma," said Anish Suri, Ph.D., chief scientific officer of Cue Biopharma. "The Phase 1 clinical trial is designed with a translational approach to determine CUE-101's ability to selectively activate and expand patients' own endogenous HPV16-specific T cell repertoire to target tumor cells. Historically, the majority of focus for cancer immunotherapy has been on broad, non-specific immune modulation or highly complex ex vivo cell therapies that are time consuming and cumbersome to produce. CUE-101 is a highly stable protein engineered to mimic the activity of antigen-presenting cells to interact directly with the existing T cells in the body that are specific for the HPV epitope driving the HNSCC. Upon binding, CUE-101 provides the necessary signals, in this case IL-2 that cause naturally occurring T cells in the patient's body to proliferate and target the tumor. This trial is unique in that the T cells act as the target of the drug treatment as well as the therapeutic itself. Importantly, our pipeline candidates, derived from the Immuno-STAT platform, can be injected directly into the patient's body and do not involve ex vivo manipulation of T cells. We believe that through our approach, the true potential of a patient's own immune system may be realized in the fight against cancer."

The trial ([NCT03978689](#)) is a multi-center, open-label, Phase 1 dose escalation and expansion study evaluating the safety, anti-tumor effect, and immunogenicity of CUE-101 as a monotherapy in patients with confirmed HPV16-driven recurrent/metastatic HNSCC and HLA-A*02:01 serotype. The study is designed to enroll approximately 50 patients. Based on translational analysis/data from the trial, the company may expand the study to test CUE-101 both as a neoadjuvant therapy and potentially in combination with checkpoint inhibitors in patients with HPV16-driven recurrent/metastatic HNSCC.

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 antigen 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.

About CUE-100 Series

Product candidates developed within the CUE-100 series are designed to selectively target tumor-specific T cells peptide-MHC complexes (pMHC) in combination with interleukin 2 (IL-2), which together are critical to the activation, expansion and survival of T cells. The binding affinity of IL-2 for its receptor has been attenuated to achieve preferential selective activation of tumor-specific T cells without broad systemic activation, potentially mitigating the dose-limiting toxicities associated with current IL-2-based therapies.

The lead program from the CUE-100 series, CUE-101, contains IL-2 and a pMHC composed of HLA-A*02:01 complexed with a dominant peptide derived from the human papilloma virus 16 E7 protein (HPV16-E7). The drug is a fusion protein biologic designed to target and activate antigen-specific T cells to attack HPV-driven cancers.

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 the pMHC T cell receptor (TCR) interaction, 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 in vivo, they are fundamentally different from other T cell therapeutic approaches, which require the patients' T cells to be extracted, then 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, 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.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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