Cue Biopharma Begins Dosing Cohort 5 in an Ongoing Phase 1 Monotherapy Trial of CUE-101 in HPV+ Recurrent/Metastatic Head and Neck Cancer

July 28, 2020

- *CUE-101 advances to cohort 5 following Safety Review Committee assessment of expanded cohort 4*
- *Cohort 5 is fully enrolled, with first patient having been dosed on July 20*
- *Additional patients to be enrolled in cohort 4 to further characterize pharmacodynamics and clinical activity in support of selecting a recommended Phase 2 dose*

CAMBRIDGE, Mass., July 28, 2020 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (NASDAQ: CUE), a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics designed to selectively engage and modulate targeted T cells within the body, announced today it has advanced CUE-101 into cohort 5 in its ongoing multicenter, open-label, dose escalation Phase 1 monotherapy trial in patients with human papilloma virus-positive recurrent/metastatic head and neck squamous cell carcinoma (HPV+ HNSCC) (NCT03978689).

Patients in cohort 5 will receive 2 mg/kg of CUE-101, which is two times the CUE-101 dose of 1 mg/kg in cohort 4. The first patient in cohort 5 received their dose and has been monitored for the initial protocol safety period of seven days with no evidence of adverse reactions. The next two patients in cohort 5 have been identified and have been scheduled to receive their first dose of CUE-101.

As previously noted in a press release dated June 15, 2020, three additional patients were enrolled in cohort 4 at the recommendation of the Safety Review Committee to further characterize immune activity and confirm safety after one of the first three patients in cohort 4 experienced a possible treatment-related dose limiting toxicity (DLT). That patient subsequently received the next planned dose of CUE-101 at the same 1.0 mg/kg dosage without an observed adverse event. As no serious (Grade 3 or higher) treatment-related adverse events were observed during a 21-day safety evaluation period for the three additional cohort 4 patients, Cue Biopharma received approval from the Safety Review Committee to initiate enrollment and treatment of patients in cohort 5.

“We are pleased to have enrolled three more patients in cohort 4 and to rapidly initiate cohort 5. Our progress is due, in large part, to the continued enthusiasm and support of our leading investigators during this challenging and uncertain time of COVID-19,” said Ken Pienta, M.D., acting chief medical officer of Cue Biopharma. “In parallel to evaluating CUE-101 at the cohort 5 dose level, we have identified additional patients to be enrolled in a further expansion of up to nine patients in cohort 4, as permitted per protocol. This allows us to further enhance our understanding of the pharmacokinetics (PK), pharmacodynamics (PD), and clinical activity of CUE-101 at what we believe could be a clinically active dose.”

To date, sixteen patients have been dosed in the Phase 1 trial. Apart from a patient in cohort 4 with a possible treatment-related Grade 3 DLT as mentioned above, there have been no other DLTs. Importantly, the Grade 3 DLT and all other reported adverse events have resolved without further complications. To date, there have been no patient discontinuations from the trial due to adverse events.

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 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, infectious diseases 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.cuebiopharma.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,” “potential,” “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 attractive therapeutic window potential, 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; potential setbacks in our research and development efforts including negative or inconclusive results from our preclinical studies; 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; adverse effects caused by public health pandemics, including COVID-19, including possible effects on our operations and clinical trials; 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 collaborators, contract research organizations, suppliers and other business partners; 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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