Cue Biopharma Provides Update on Ongoing Phase 1 Trial Evaluating CUE-101 in Recurrent/Metastatic Head and Neck Cancer

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- *Patient enrollment and data generation remain on schedule with 13 patients having received CUE-101 to date and enrollment continues per protocol to identify a recommended Phase 2 dose*
- *Dose-proportional increases in drug exposure combined with observations demonstrating pharmacodynamic biomarkers in peripheral blood and clinical data from scans bolsters confidence in potential for attractive therapeutic window*

CAMBRIDGE, Mass., June 15, 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, is providing an update on its Phase 1 trial of CUE-101 monotherapy as second-line or later therapy for patients with HPV+ recurrent and/or metastatic head and neck squamous cell carcinoma (HNSCC).

As of June 15, 2020, the ongoing Phase 1, first-in-human, multicenter trial has enrolled 13 patients, with a majority of patients having received multiple cycles of therapy. In cohorts 1 through 4, patients received dosages of 0.06 mg/kg, 0.18 mg/kg, 0.54 mg/kg and 1.0 mg/kg, respectively. Out of the 13 patients enrolled, there are six patients presently remaining on study for ongoing data generation.

As recently presented by Daniel Passeri, chief executive officer of Cue Biopharma, at the Jefferies Healthcare Conference on June 4, preliminary observations include:

- Pharmacokinetic data indicating drug exposure that is in line with preclinical projections and is dose-proportional; furthermore, comparable exposures have been observed upon repeated administration
- Pharmacodynamic data indicating selective expansion of the targeted T cells in the peripheral blood of several patients across cohorts 2 and 3; evaluation of activity in patients from cohort 4 is ongoing
- Preliminary radiographic evidence indicating CUE-101 is clinically active, with a patient from cohort 2 experiencing reduction of target lesion following two cycles of CUE-101 that was sustained through day 84 of treatment, at which point the patient was confirmed as having stable disease; this patient continues to be on study

To date, CUE-101 has been overall well-tolerated with treatment-related adverse events (AEs) primarily being mild-to-moderate (Grade 1 or 2) with no discontinuations due to AEs. One patient from dose cohort 4 at 1.0 mg/kg experienced a Grade 3 adverse event (anemia and fatigue) that was reported on day 19 of the 21-day safety evaluation period. Of note, this patient had an underlying condition, and following a blood transfusion the anemia resolved, allowing for the patient to receive the second planned dose of CUE-101 at the same 1.0 mg/kg dose on June 8 which to date, appears to have been well tolerated. This patient remains on study. On June 5, the Safety Review Committee designated this event as a possible drug-related dose limiting toxicity (DLT), and thus an additional three patients will be enrolled at the 1.0 mg/kg dose level within cohort 4 per protocol. This will allow for a more thorough evaluation of CUE-101 pharmacodynamics and clinical activity in order to better define the therapeutic window. The fourth patient in cohort 4 has received their cycle 1 dose and the other two patients have been identified and are scheduled to receive their first dose of CUE-101 before the end of this month. If no additional DLTs emerge within these three additional patients, the company will proceed to the cohort 5 dose.

“Based on the preliminary safety, tolerability, biomarker metrics and clinical activity observed to date, we are highly encouraged that CUE-101 appears to have an attractive therapeutic window. We are looking forward to launching our combination trial with Merck’s Keytruda® (pembrolizumab) as well as a neo-adjuvant trial later this year to generate clinical data sets pertaining to tumor-infiltrating lymphocytes, or TILs, from the targeted T cell population,” said Ken Pienta, M.D., acting chief medical officer. “Moreover, based on our collective data to date, we are now well-positioned to further exploit the flexibility of our trial design which allows us to expand any given dose level up to nine patients, further enhancing the supporting data evaluating the drug’s safety and therapeutic window. This will enable us to select the optimal dose to be advanced into Part B of the Phase 1 trial.”

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 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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