Cue Biopharma Granted FDA Fast Track Designation for CUE-101 for the Treatment of Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma

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BOSTON, Oct. 04, 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 tumor-specific T cells directly within the patient's body, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to CUE-101, its lead clinical drug candidate from the CUE-100 series of interleukin 2 (IL-2)-based biologics, for the treatment of patients with human papilloma virus (HPV16+) recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) as a monotherapy and in combination with pembrolizumab (KEYTRUDA®).

"We are very pleased to have received Fast Track designation from the FDA for CUE-101. This designation not only underscores the large unmet need for patients with R/M head and neck cancer who currently rely on available non-targeted therapies, but also highlights the potential of CUE-101 to provide a significant clinical benefit," said Dr. Matteo Levisetti, senior vice president, Clinical Development of Cue Biopharma. "To date in its Phase 1b clinical trials, CUE-101 has demonstrated a favorable tolerability profile and single-agent anti-tumor activity in monotherapy as well as encouraging anti-tumor clinical activity in combination with pembrolizumab, supporting the potential to improve overall survival (OS) for these patients. We look forward to providing periodic updates and remain committed to advancing the development of CUE-101 to provide patients with a potentially more effective and better tolerated treatment option. We anticipate initiating a registrational trial for CUE-101 monotherapy by mid-2023."

Fast Track is a process designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fulfill an unmet medical need. A therapeutic candidate that receives Fast Track designation may be eligible for more frequent interactions with the FDA to discuss the therapeutic candidate's development plan. Therapeutic candidates with Fast Track designation may be eligible for accelerated approval and priority review if supported by clinical data.

CUE-101 is currently being evaluated in a Phase 1b trial (NCT03978689) as a monotherapy for the treatment of second line and beyond patients with HPV16+ R/M HNSCC and as a first-line treatment in a Phase 1 dose escalation and expansion trial in combination with KEYTRUDA® for the same patient population.

About HPV+ Recurrent or Metastatic Head and Neck Cancer
Human papilloma virus (HPV)-positive 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 standard of care, the majority of patients with metastatic disease will experience recurrence, significantly affecting quality of life and often leading to untimely death.

About CUE-101
CUE-101 is Cue Biopharma's lead clinical drug candidate from the CUE-100 series of interleukin 2 (IL-2)-based biologics. It is designed to activate and expand HPV16 tumor-specific T cells by presenting two signals or "cues" to T cells. Signal #1 incorporates the HPV E7 protein, harbored by HPV-induced cancer cells, to provide selectivity through interaction with the HPV-specific T cell receptor. Signal #2 consists of an engineered IL-2 variant to stimulate the activity of T cells. To date, Cue Biopharma has established initial proof of concept with CUE-101 as a monotherapy and believes that the CUE-100 series has the potential to treat multiple cancer indications. CUE-101 is currently being evaluated for the treatment of HPV16+ driven R/M HNSCC as a monotherapy and in combination with pembrolizumab (KEYTRUDA®).

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate tumor-specific T cells directly within the patient's body to transform the treatment of cancer. 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 Boston, 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 Company's beliefs about the potential benefits of CUE-1010 and the CUE 100 series; the Company's projections regarding the timing for clinical trial initiation; and the company's business strategies, plans and prospects. 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. All statements other than statements of historical facts included in this press release regarding the company's strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. 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 a history of losses; the company's ability to achieve profitability; potential setbacks in the company's research and development efforts including negative or inconclusive results from its preclinical studies, 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 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; operations and clinical 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 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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