Cue Biopharma Presents Updated Data from Phase 1 Trial of CUE-101 in Recurrent/Metastatic HPV+ Head and Neck Cancer at the 2024 ASCO Annual Meeting

June 4, 2024

- *Overall response rate (ORR) of 46% and 12-month overall survival (OS) of 96% in first line (1L) recurrent/metastatic (R/M) HPV+ head and neck squamous cell carcinoma (HNSCC) treated with CUE-101 and KEYTRUDA® (pembrolizumab)*
- *Median overall survival (mOS) of 20.8 months in second line (2L) and beyond HPV+ HNSCC patients treated with CUE-101 monotherapy compared with historical mOS of 7.5 and 8.4 months for third-party checkpoint inhibitor trials in 2L R/M HNSCC: CheckMate 141 and KEYNOTE-040*
- *CUE-101 data will be presented in an oral presentation at ASCO today*

BOSTON, June 04, 2024 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of therapeutic biologics to selectively engage and modulate disease-specific T cells, today announced updated data from its ongoing Phase 1 trial evaluating its lead oncology asset from the CUE-100 series of biologics, CUE-101. The data will be presented in an oral presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting today June 4, 2024, in Chicago, IL.

Oral Presentation Details:
Abstract Number: 6004
Session Type and Title: Oral Abstract Session; Head and Neck Cancer
Session Date and Time: June 4, 2024, 9:45 AM-12:45 PM CDT
Title: A phase 1 dose-escalation and expansion study of CUE-101, given as monotherapy and in combination with pembrolizumab in patients with recurrent/metastatic HPV16+ head and neck squamous cell cancer (R/M HNSCC).
Presenter: Douglas R. Adkins, M.D., Professor of Medicine, Washington University School of Medicine

In addition, on Saturday, June 1, 2024, the Company presented a poster on its second clinical asset from the CUE-100 series, CUE-102, in which data-to-date has demonstrated expansion of Wilms' Tumor 1 (WT1)-specific T cells, anti-tumor activity and favorable tolerability.

"The objective response rate observed with CUE-101 and pembrolizumab is very encouraging. The combination was well-tolerated, and responses appeared to be durable," said Douglas R. Adkins, M.D., Professor, Division of Oncology at the Washington University School of Medicine in St. Louis, and a principal investigator participating in the CUE-101 clinical trial. "These results appear to support the continued development of CUE-101 with the potential of CUE-101 providing an improved treatment alternative for this patient population."

Key data highlights to date from the expansion portion of the trial evaluating CUE-101 at the recommended Phase 2 dose (RP2D) of 4mg/kg in combination with pembrolizumab with 24 evaluable 1L patients (data cutoff of May 1, 2024):

- ORR of 46% and Disease Control Rate (DCR) of 79% in patients with combined positive score (CPS) ≥1, compared to an ORR of 19% observed with pembrolizumab alone in the historical third-party KEYNOTE-048 trial. This includes one complete response (CR) and 10 partial responses (PR), in addition to eight durable stable diseases (DSD) of >12 weeks.
- 12-month overall survival (OS) of 96%.
- Median progression free survival (PFS) of 5.8 months compared to 3.2 months with pembrolizumab alone in the third-party KEYNOTE-048 trial.

Key data highlights from the CUE-101 expansion portion of the Phase 1b trial evaluating CUE-101 at the RP2D as monotherapy with 20 evaluable 2L+ patients (majority 3L+):

- mOS of 20.8 months, notably longer than the historical mOS of 7.5 and 8.4 months reported in third-party 2L R/M HNSCC trials: CheckMate 141 and KEYNOTE-040, respectively.

No unanticipated, significant safety concerns have emerged in either the combination or monotherapy trials, and adverse events have been readily managed with appropriate medical care.

Matteo Levisetti, M.D., chief medical officer of Cue Biopharma added, "We are pleased with the clinical activity observed in patients treated with CUE-101 in combination with pembrolizumab. We believe that the data provide a strong foundation for further development, supporting our goal of bringing a new treatment option to this patient population."

Key data highlights to date from the fully enrolled CUE-102 dose escalation part of the Phase 1 clinical trial (data cutoff of May 1, 2024) include:

- DCR of 43.5%
- Two patients at the 2mg/kg dose, one with gastric cancer and one with ovarian cancer have demonstrated reductions in tumor burden.
- Selective expansion of WT1-specific T cells in multiple patients.
- No dose-limiting toxicities or drug-related serious adverse events have been reported to date in patients treated during the dose escalation phase at doses ranging between 1-8mg/kg of CUE-102.
- Expansion at CUE-102 4mg/kg is ongoing.

The CUE-101 oral presentation and CUE-102 poster presentation will be available in the Investors & Media section of the Company's website at www.cuebiopharma.com under Scientific Publications and Presentations, following ASCO.

About the CUE-100 Series
The CUE-100 series consists of Fc-fusion biologics that present two signals to T cells. Signal #1 is a tumor-specific peptide linked to a major histocompatibility complex (pMHC) to enable selectivity and specificity. Signal #2 is a rationally engineered interleukin 2 (IL-2) molecule to trigger T cell activation. These singular biologics are anticipated to selectively target, activate and expand a robust repertoire of tumor-specific T cells directly in the patient's body. 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 the 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-101 and the Phase 1 trial
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 the HPV E7 protein to the HPV-specific T cell receptor. CUE-101 is currently being evaluated in a fully enrolled Phase 1 open-label, dose escalation and expansion study, for the treatment of HPV16+ driven recurrent/metastatic head and neck squamous cell carcinoma in second line (2L) and beyond patients as a monotherapy, and as a first line (1L) therapy in combination with pembrolizumab (KEYTRUDA®).

About CUE-102 and the Phase 1 trial
CUE-102 is Cue Biopharma's second lead clinical drug candidate from the CUE-100 series of interleukin 2 (IL-2)-based biologics. It is designed to activate and expand Wilms' Tumor 1 (WT1)-specific T cells by presenting the WT1 peptide to the WT1- specific T cell receptor. WT1 is a well-recognized onco-fetal protein known to be over-expressed in a number of cancers, including solid tumors and hematologic malignancies. CUE-102 is being evaluated in a Phase 1 open label, two-part dose escalation and expansion study, for patients with late-stage colorectal, gastric/gastroesophageal junction, pancreatic and ovarian cancers that express WT1.

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body. The company's proprietary platform, Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* and biologics are designed to harness the curative potential of the body's intrinsic immune system through the selective modulation of disease-specific T cells without the adverse effects of broad systemic immune modulation.

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 X and LinkedIn.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, those regarding: the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells and the applicability of the company's platform across many cancers and autoimmune diseases; the company's business strategies, plans and prospects, including potential clinical paths for CUE-101; and the Company's expectations regarding the potential benefits of, and prospects for, its drug candidates, including CUE-101 and CUE-102. 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 or clinical trials or the company's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; serious and unexpected drug-related side effects or other safety issues experienced by participants in clinical trials; 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 possible effects on the company's operations and 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 and ability to continue as a going concern; 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 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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