# Cue Biopharma Presents Positive Data Update from Ongoing Phase 1 Trials of CUE-101 for Recurrent/Metastatic HPV+ Head and Neck Squamous Cell Carcinoma at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

May 25, 2023

- *As of the data cutoff date, nine of the 14 evaluable patients treated with CUE-101+ KEYTRUDA® (pembrolizumab) demonstrated tumor regression, with five confirmed partial responses (PRs) and three durable stable disease (DSD) responses, two of which have tumor burden reductions of -18% and -24% and remain on treatment*
- *100% of patients treated with CUE-101+ pembrolizumab at the recommended phase 2 dose (RP2D) of 4mg/kg (n=16) remain alive to date following treatment*
- *As of the data cutoff date, CUE-101 as monotherapy at the RP2D of 4mg/kg demonstrated median overall survival (mOS) approaching 14 months, in third line and beyond (3L+) patients, ~6 months longer than reported with current standard of care in second line (2L) patients*
- *Clinical data supports potential registrational paths for both CUE-101 as a monotherapy in 3L+ R/M HPV16+ HNSCC, and CUE-101+ pembrolizumab in first line (1L) R/M HPV16+ HNSCC*

BOSTON, May 25, 2023 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body, announced today the presentation of a positive data update from its ongoing Phase 1 clinical trials evaluating its lead biologic from the IL-2-based CUE-100 series, CUE-101, 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. The data will be presented in a poster by Dr. Christine Chung, M.D., Chair, Department of Head and Neck-Endocrine Oncology, Moffitt Cancer Center on June 5, 2023 at the ASCO Annual Meeting in Chicago, IL. In addition, the poster will also be highlighted by an expert head and neck cancer panel during a Poster Discussion Session immediately following the scheduled poster presentation.

"CUE-101 clinical data to date continues to demonstrate both promising evidence of single-agent activity as well as complementary activity in combination with checkpoint inhibitor pembrolizumab." said Matteo Levisetti, M.D., chief medical officer of Cue Biopharma. "Based on the strength of the data to date, we believe CUE-101 has the promise to be a potential therapeutic advancement for patients battling head and neck cancer, a devastating disease of unmet medical need, with potential registrational paths both as monotherapy and in combination with pembrolizumab."

**Key data highlights from the Phase 1b trial in combination with pembrolizumab at the RP2D of 4mg/kg, with 14 evaluable patients as of the data cutoff date of May 15, 2023 include:**

- Overall response rate of ~40% with 4 out of 5 confirmed PRs occurring in tumors with low PD-L1 expression as evidenced by combined positive scores (CPS) of 20 or less
- Importantly, all 5 patients with a confirmed PR demonstrated >99% reduction in circulating cell-free HPV DNA (HPV cfDNA)
- Median duration of response is 35 weeks with a median progression free survival (PFS) approaching 5 months

**Key data highlights from the Phase 1b CUE-101 monotherapy patient expansion portion of the trial at the RP2D of 4mg/kg to date, include:**

- Current mOS approaching 14 months compares favorably to the historical mOS of 7.5 and 8.4 months reported from third-party clinical trials with checkpoint inhibitors in 2L R/M HNSCC in CheckMate 141[1] and KEYNOTE-040 respectively[2]
- CUE-101 has been well tolerated to date as monotherapy and in combination with pembrolizumab
- Durable PR greater than 9 months and 6 DSD including a patient remaining on therapy for ~2 years, resulting in an overall clinical benefit rate of 35%

Dan Passeri, chief executive officer of Cue Biopharma, added, "Overall, the emerging data supports the potential of CUE-101 to provide patients with an enhanced disease control rate. We look forward to continuing to evaluate responses in these patients in addition to assessing the registrational trial options for CUE-101. Furthermore, the observed evidence of single agent activity in late-stage patients and the complementary mechanism of action in combination with checkpoint inhibition holds the potential to enhance anti-tumor activity across a broad range of cancers with our Immuno-STAT ™ platform."

**Presentation Details**
**Title:** A phase 1 dose-escalation and expansion study of CUE-101, a novel HPV16 E7-pHLA-IL2-Fc fusion protein, given as monotherapy and in combination with pembrolizumab in patients with recurrent/metastatic HPV16+ head and neck cancer.
**Abstract Number:** 6013
**Session:** Head and Neck Cancer
**Poster Session Display Date and Time:** June 5, 2023, 1:15 PM-4:15 PM CDT
**Presenter:** Christine Chung, M.D., Moffit Cancer Center

**Poster Discussion Session Date and Time:** June 5, 2023, 4:30 PM-6:00 PM CDT
**Discussant:** Erminia Massarelli, M.D., Ph.D., City of Hope Comprehensive Cancer Center

The poster will be available in the Investor & Media section of the Company's website at www.cuebiopharma.com under Scientific Publications and Presentations, following the presentation.

The Company will host an Investor Update call on Wednesday, June 14, 2023 to review and discuss the clinical progress and associated data presented at ASCO on June 5. Call details will be issued prior to the event.

**References:**


[1.] *Ferris, R.L. (Oct 2016) Nivolumab for Recurrent Squamous-Cell Carcinoma of the Head and Neck (CheckMate-141): a randomized, open-label, phase 3 study. The New England Journal of Medicine 2016; 375:1856-67.DOI: 10.1056/NEJMoa1602252*

[2.] *Cohen, EW E. (Nov 2018) Pembrolizumab versus methotrexate, docetaxel, or cetuximab for recurrent or metastatic head-and-neck squamous cell carcinoma (KEYNOTE-040): a randomized, open-label, phase 3 study. The Lancet, DOI: http://dx.doi.org/10.1016/S0140-6736(18)31999-8*


**About ASCO**
Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to the principle that knowledge conquers cancer. Together with the Association for Clinical Oncology, ASCO represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of high quality, equitable patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. The ASCO Annual Meeting is a unique and unparalleled opportunity to connect with one of the largest, most diverse audiences in global cancer care as well as global cancer experts and professionals, to discover the latest innovations in cancer research and education.

**About HPV+ Recurrent or Metastatic Head and Neck Cancer**
Head and neck squamous cell carcinomas (HNSCC) are the 8th most common cancer in the world. A significant subset of the cases of HNSCC includes human papillomavirus (HPV) associated oropharyngeal tumors, with HPV16 detectable in 80%-90% of these cases. Despite the current standard of care treatments, more than 50% of patients with advanced HNSCC will experience recurrence, representing a significant unmet need.

**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'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 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 body's intrinsic immune system as T cell engagers without the need for ex vivo manipulation or broad systemic 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 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-101 and the CUE 100 series; the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells; 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; the Company's inability to replicate in later clinical trials any positive data demonstrated in earlier 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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