



Cue Biopharma Reports Two Objective Responses (1 cPR and 1uPR) in First Interim Update from Dose Escalation Portion of Ongoing Phase 1 Combination Study of CUE-101 and KEYTRUDA® in First Line Patients with HPV+ Recurrent/Metastatic Head and Neck Cancer

January 26, 2022

- *Early data in the combination study of CUE-101 and KEYTRUDA® (pembrolizumab) supports synergistic activity; of four patients treated in dose escalation in the 2mg/kg and RP2D 4mg/kg cohorts, two have partial responses (1 confirmed and 1 unconfirmed) and two are manifesting reductions in target lesions*
- *Updated CUE-101 monotherapy data further enhances confidence in potential as single agent therapeutic with 50% clinical benefit rate reported to date in RP2D (4mg/kg) expansion monotherapy trial and an emerging enhanced overall survival rate that supports the premise that CUE-101 selectively stimulates cancer-relevant CD8+ T cells*

CAMBRIDGE, Mass., Jan. 26, 2022 (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 directly within the patient's body, will provide a clinical update during today's conference call and webcast at 4:30 p.m. EST. Live and archived versions of the event can be accessed via the Company's [website](#).

Members of the Cue Biopharma executive management team will provide an update from the Company's ongoing clinical trials with CUE-101, its lead and representative IL-2 based drug product candidate from the CUE-100 series. CUE-101 is currently in a Phase 1b clinical trial for the treatment of third line and beyond HPV+ recurrent/metastatic head and neck squamous cell carcinoma. The discussion will focus on recent data updates from the Phase 1b monotherapy dose expansion trial and the dose escalation combination trial evaluating CUE-101 front line with Merck's KEYTRUDA® (pembrolizumab). Management will also provide an update on the Company's pipeline development progress from the IL-2 based CUE-100 series including CUE-102, with an Investigational New Drug (IND) filing planned for the first quarter of 2022, as well as updates on its strategic objectives and anticipated milestones.

Webcast Details

Wednesday, January 26, 2022 at 4:30 p.m. EST

Investors: 877-407-9208

International: 201-493-6784

Conference ID: 13726509

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1525411&tp_key=7a7d92f501

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 directly within the patient's body to transform the treatment of cancer, infectious disease and autoimmune disease. 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, the company is 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, 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 estimate of the period in which it expects to have cash to fund its operations; 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; 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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