Cue Biopharma Granted U.S. Patents on Lead Clinical Program Novel Drug Product Candidate CUE-101

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Patents Further Strengthen and Enhance Intellectual Property (IP) Portfolio

CAMBRIDGE, Mass., Sept. 21, 2021 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (NASDAQ: CUE), a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells directly within the body, announced today the issuance of two new United States Patents Nos. 11,117,945 and 11,104,712 from the United States Patent and Trademark Office.

U.S. Patent No. 11,117,945 covers Cue Biopharma's first clinical drug candidate, CUE-101, and its use in treating HPV16-associated cancers such as head and neck, cervical, and genitoanal cancers. CUE-101 is currently in a Phase 1b clinical trial in which second line and beyond patients are receiving CUE-101 as a monotherapy for HPV16+ recurrent/metastatic head and neck squamous cell carcinoma (HNSCC). To date, CUE-101 has demonstrated monotherapy clinical activity by selective activation of targeted CD8+ T cells specific for HPV+ cancer cells with a 40% clinical benefit in the first 10 evaluable patients at the recommended Phase 2 dose of 4mg/kg. CUE-101 is also in a dose escalation study in combination with pembrolizumab in front-line patients with HPV16+ recurrent/metastatic HNSCC. A Phase 2 exploratory clinical trial in which CUE-101 will be administered in the neoadjuvant phase before standard of care (SOC) therapy in treatment-naïve, HLA-A*0201 positive patients with locally advanced, HPV-positive oropharyngeal squamous-cell carcinoma, is expected to begin enrolling patients this fall.

The second U.S. Patent, No. 11,104,712, covers the use of CUE-101 in combination with KEYTRUDA® (pembrolizumab) for treating HPV16-associated cancers such as head and neck, cervical, and genitoanal cancers. The combination of CUE-101 and pembrolizumab is being evaluated by Cue Biopharma in collaboration with Merck Sharp & Dohme Corp.

"The issuance of these patents represents an important development as we continue to build-up our IP portfolio and bolster patent protection for the novel protein engineering platforms we have enabled, particularly as we begin demonstrating clinical activity in what we believe will be a disruptive and transformational breakthrough in immunotherapy for addressing cancer and other debilitating and life-threatening diseases," said Daniel Passeri, chief executive officer of Cue Biopharma. "Furthermore, obtaining these patents early in the clinical development of CUE-101 enhances our ability to receive a Patent Term Extension from the United States Patent and Trademark Office if CUE-101 is approved by the FDA. We continue to make a substantial investment in protecting our intellectual property, and we look forward to the issuance of additional patents that cover our important platforms and pipeline products."

Cue Biopharma's IP portfolio includes approximately 300 pending applications and issued patents that are either owned by Cue Biopharma or exclusively licensed from the Albert Einstein College of Medicine.

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 https://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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