Cue Biopharma Reports Second Quarter 2021 Results, Recent Data Updates of CUE-101 Phase 1 Dose Escalation and Expansion Study, Platform Progress and Business Highlights

August 17, 2021

CAMBRIDGE, Mass., Aug. 17, 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 within the patient's body, provided a business and clinical progress update for the second quarter 2021.

"During the second quarter 2021, we continued to make significant clinical progress advancing our IL-2 based CUE-100 series, represented by the Phase 1a/1b monotherapy trial of CUE-101 and combination-therapy trial with KEYTRUDA® (pembrolizumab). In addition, we have continued with the development and expansion of our pipeline programs and technology platforms, and also enhanced our capital resources," said Daniel Passeri, chief executive officer of Cue Biopharma. "Importantly, we recently reported a confirmed partial response (PR) in a patient from our ongoing Phase 1 monotherapy dose escalation trial of CUE-101 and look forward to providing further details on this patient response during the quarterly update call. Our Phase 1 monotherapy dose escalation and expansion study is now in dose expansion and our combination study with pembrolizumab continues in dose escalation. During the call, we will also highlight the development implications for CUE-101 and potential of the CUE-100 series and Immuno-STAT™ platform."

Kerri-Ann Millar, chief financial officer of Cue Biopharma, added, "We continue to be in a solid financial position and deployed our at-the-market (ATM) common stock facility during the second quarter to extend the anticipated operational runway further into the fourth quarter of 2022."

Recent News & Business Updates

- Reported first patient dosed in the Part B expansion of its CUE-101 Phase 1 monotherapy clinical trial in HPV+ second line and beyond head and neck squamous cell carcinoma (HNSCC), at the recommended Phase 2 dose of 4mg/kg.
- Presented preclinical data on CUE-401, the Company's first autoimmune drug product candidate from the CUE-400 series, at the 2021 Federation of Clinical Immunology Societies (FOCIS) Annual Meeting.

Second Quarter 2021 Financial Results

The Company reported collaboration revenue of approximately $2.7 million and $1.1 million for the three months ended June 30, 2021 and 2020, respectively. The increase in collaboration revenue of $1.6 million was primarily due to additional research and development and contract manufacturing activities in preparation of an investigational new drug (IND) filing for its second drug product candidate from the IL-2 based CUE-100 series, CUE-102, planned for the first half of 2022.

Research and development expenses were $8.8 million and $8.1 million for the three months ended June 30, 2021 and 2020, respectively. The increase in research and development expenses of $0.7 million was primarily due to an increase in laboratory and drug substance manufacturing costs and clinical expenses.

General and administrative expenses were $4.3 million and $3.9 million for the three months ended June 30, 2021 and 2020, respectively. The increase in general and administrative expense of $0.4 million was primarily due to an increase in stock-based compensation expense and legal fees incurred in the second quarter of 2021 as compared to the same period in 2020.

Cue Biopharma, Inc.
Selected Consolidated Statement of Operations Data
(in thousands)

	Three Months Ended June 30,	
	2021	**2020**
Collaboration revenue	$ 2,739	$ 1,075
Operating expenses:		
General and administrative	4,280	3,898
Research and development	8,762	8,119
Total operating expenses	13,042	12,017
Loss from operations	$ (10,303)	$ (10,942)
Other income:		
Interest income, net	24	109
Net Loss	$ (10,279)	$ (10,833)
Net loss per common share – basic and diluted	$ (0.33)	$ (0.38)
Weighted average common shares outstanding – basic and diluted	31,233,794	28,221,537

Cue Biopharma, Inc. Selected Consolidated Balance Sheet Data (in thousands)		
	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 73,920	$ 74,866
Marketable securities	-	10,003
Total current assets	$ 79,677	$ 87,527
Working capital	$ 63,004	$ 71,212
Total assets	$ 89,672	$ 99,533
Total stockholders' equity	$ 72,910	$ 78,911

Webcast Details
Tuesday, August 17, 2021 at 4:30 p.m. EDT
Investors: 877-407-9208
International: 201-493-6784
Conference ID: 13721829
Webcast: http://public.viavid.com/index.php?id=145891

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 the Private Securities Litigation Reform Act of 1995 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 plans to submit an IND for CUE-102; 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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Source: Cue Biopharma, Inc.