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

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CAMBRIDGE, Mass., May 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 first quarter 2021.

"During the first quarter of 2021 and early second quarter, we continued to make significant progress advancing the Phase 1a/1b monotherapy trial of CUE-101 and continued development of our expanding pipeline and technology platforms, as well as enhancing 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 as well as describing the development implications for CUE-101 and potential of the CUE-100 series and Immuno-STAT™ platform, during the quarterly update call."

Kerri-Ann Millar, chief financial officer of Cue Biopharma, added, "We finished the first quarter of 2021 in a solid financial position which was further strengthened by the deployment of our at-the-market (ATM) common stock facility in April that enabled us to boost our cash position by an additional $10.4 million giving us operational runway into the fourth quarter of 2022."

Recent News & Business Updates

- Reported PR in one patient and stable disease (SD) in five patients, confirmed by RECIST criteria, providing evidence of single-agent clinical activity of CUE-101 in the ongoing Phase 1 monotherapy dose escalation trial in late stage second-line and beyond patients with HPV+ recurrent/metastatic head and neck cancer, as well as evidence of both tumor-specific CD8+ T cell expansion and dose-dependent increases in NK cells.

- Extended cash runway with sales in April of an aggregate of $10.4 million shares of our common stock pursuant to our ATM equity offering sales agreement with Stifel. As of April 30, 2021, we sold a cumulative total of 2,099,700 shares of common stock for aggregate net proceeds of $32.7M, net of commissions paid, under the sales agreement.

- Initiated Phase 1 dose escalation clinical trial of CUE-101 in combination with Merck's KEYTRUDA ®, an anti-PD-1 biologic agent, as first-line therapy in patients with advanced HPV16+ head and neck cancer.

- Appointed renowned experts Abul K. Abbas, M.D., distinguished professor in pathology and former chair of the department of pathology at the University of California, San Francisco (UCSF) and Michael Kalos, Ph.D., managing director of Next Pillar Consulting, LLC and former executive vice president and head of research and development at ArsenalBio, to our Scientific Advisory Board (SAB).

First-Quarter 2021 Financial Results

The Company reported collaboration revenue of approximately $1.6 million and $0.9 million for the three months ended March 31, 2021 and 2020, respectively.

Research and development expenses were $9.8 million and $9.9 million for the three months ended March 31, 2021 and 2020, respectively. The decrease in research and development expenses of $0.9 million was primarily due to a decrease in laboratory and drug substance manufacturing costs as the clinical supply for our lead drug candidate, CUE-101, was produced during 2020, as well as a reduction in clinical and travel related expenses.

General and administrative expenses were $4.3 million and $4.0 million for the three months ended March 31, 2021 and 2020, respectively. The increase in general and administrative expense of $0.3 million was primarily due to an increase in stock-based compensation expense and legal fees incurred in the first 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 March 31,	
	2021	**2020**

Collaboration revenue	$ 1,553	$ 900
Operating expenses:		
General and administrative	4,255	3,989
Research and development	9,816	9,906
Total operating expenses	14,071	13,895
Loss from operations	(12,518)	(12,995)
Other income:		
Interest income, net	13	177
Net Loss	$ (12,505)	$ (12,818)
Net loss per common share – basic and diluted	$ (0.41)	$ (0.48)
Weighted average common shares outstanding – basic and diluted	30,434,525	26,569,681

Cue Biopharma, Inc.
Selected Consolidated Balance Sheet Data
(in thousands)

	March 31, 2021	December 31, 2020
Cash and cash equivalents	73,257	74,866
Marketable securities	-	10,003
Total current assets	77,405	87,527
Working Capital	60,772	71,212
Total assets	88,721	99,533
Total Stockholders' equity	69,669	78,911

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 diseases and autoimmune diseases. 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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