Cue Biopharma Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Business Highlights

March 16, 2021

- *Evaluated initial observations in CUE-101 Phase 1 monotherapy dose escalation clinical trial for treatment of human papilloma virus positive recurrent/metastatic head and neck squamous cell carcinoma (HPV+ R/M HNSCC), which demonstrated tolerability and generated encouraging emerging metrics pertaining to pharmacokinetic and pharmacodynamic profile, as well as early signs of anti-tumor activity*
- *Initiated dosing in Phase 1 dose escalation trial of CUE-101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), as first-line treatment for HPV+ R/M HNSCC*
- *Extended the term of the research program with Merck, for the development of clinical Immuno-STAT ™ (Selective Targeting and Alteration of T cells) candidates focused on antigen-specific modulation for the treatment of type 1 diabetes and an additional undisclosed autoimmune disease indication*
- *Presented preclinical data at SITC 2020 supporting extension of platform to WT1 and KRAS targets*
- *Discovered a novel class of therapeutic molecules with the potential for expanding induced regulatory T cells (iTregs) that could have broad applications in multiple chronic autoimmune diseases with diverse or unknown autoantigens*

CAMBRIDGE, Mass., March 16, 2021 (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, provided a business update for the fourth quarter and full year 2020.

"We have executed on our stated corporate goals and objectives for 2020, enabling us to begin 2021 on track, despite the ongoing challenges of the global pandemic. Accordingly, we marked the beginning of 2021 by the dosing of the first patient in our CUE-101 Phase 1 combination trial with KEYTRUDA, which has the potential for significant mechanistic synergies to provide broader patient reach and enhancement of patient benefit," said Dan Passeri, chief executive officer of Cue Biopharma. Mr. Passeri added, "Importantly, we are now well-positioned to execute throughout 2021 with the aim of demonstrating the potential significance of our approach for treating debilitating diseases by restoring immune balance. In oncology, we have the ongoing Phase 1 studies of CUE-101 which aim to establish a potential registration path, as well as proof-of-principle and a mitigated risk profile for the entire CUE-100 series. For autoimmune disease, we remain on-track to demonstrate the potential of deploying our CUE-300 series (partnered with Merck for defined indications) where the autoantigens are known and well characterized, e.g., type 1 diabetes. For autoimmune diseases where the autoantigens are unknown, or not well characterized, we look forward to further progressing our novel CUE-400 series, a recent development that is based on our IL-2 variant and modified TGF-beta."

Ken Pienta, M.D., acting chief medical officer of Cue Biopharma, commented, "We are pleased with the progress and observations made to date in our monotherapy trial and with the initiation of our combination trial of our lead drug candidate CUE-101. We continue to generate supportive clinical datasets from the ongoing dose escalation and expansion portion of the monotherapy trial in preparation for the Phase 1b monotherapy expansion segment of the trial scheduled to begin in the second half of 2021. Furthermore, with the initiation of the combination trial in front-line therapy with KEYTRUDA, combined with the expectation of launching our neo-adjuvant study in newly diagnosed patients later this year, we have implemented a clinical development approach that we believe will enable us to broaden patient reach and maximize the potential for enhancing therapeutic benefit."

Fourth Quarter 2020 Financial Results

The Company reported collaboration revenue of approximately $0.5 million and $1.0 million for the three months ended December 31, 2020 and 2019, respectively. The decrease was primarily due to adjustments in the LG Chem, Ltd. and Merck collaboration budgets and full-time employee allocations.

Research and development expenses were $8.0 million and $7.0 million for the three months ended December 31, 2020 and 2019, respectively. The increase was due to clinical trial activity for the CUE-101 monotherapy and combination clinical trials, hiring of research and development personnel in the fourth quarter of 2020, manufacturing costs for CUE-102 clinical material as well as development of the Neo-STAT™ cell line.

General and administrative expenses were $3.4 million and $3.1 million for the three months ended December 31, 2020 and 2019, respectively. The increase was due primarily to stock-based compensation and legal fees incurred during the fourth quarter of 2020.

Full Year 2020 Financial Results

The Company reported collaboration revenue of approximately $3.2 million and $3.5 million for the years ended December 31, 2020 and 2019, respectively. The decrease was primarily due to adjustments in the LG Chem Ltd., and Merck collaboration budgets and changes in the allocation of full-time employees to these programs during the year.

Research and development expenses were $33.5 million and $27.5 million for the years ended December 31, 2020 and 2019, respectively. The increase was due to clinical trial activity for the CUE-101 monotherapy and combination clinical trials, hiring of research and development personnel throughout 2020 and manufacturing costs related to CUE-101 and CUE-102 clinical material.

General and administrative expenses were $14.7 million and $12.7 million for the years ended December 31, 2020 and 2019, respectively. The increase in general and administrative expense was due primarily to stock-based compensation and legal fees offset by a decrease in travel expenses as the COVID-19 pandemic continued to hamper business travel throughout 2020.

As of December 31, 2020, the Company had approximately $84.9 million in cash and cash equivalents compared with $59.4 million as of December 31, 2019.

Recent News & Business Updates

- Evaluated initial observations in CUE-101 Phase 1 monotherapy dose escalation clinical trial for treatment of HPV+ R/M HNSCC, which demonstrated tolerability and generated encouraging emerging metrics pertaining to pharmacokinetic and pharmacodynamic profile, as well as early signs of anti-tumor activity. Compilation of data to date supports our belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells.

- Dosed the first patient in a Phase 1 dose escalation clinical trial of CUE-101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), as first-line treatment for HPV+ R/M HNSCC, which is being conducted in parallel at the same clinics that are leading the ongoing Phase 1 monotherapy study of CUE-101.

- Extended the term of the research program with Merck under the existing 2017 research collaboration and license agreement toward developing a clinical candidate for the treatment of type 1 diabetes and an additional undisclosed autoimmune disease indication. Under the terms of the extension, Cue Biopharma will receive additional financial research support to further study and develop promising preclinical biologics with the objective of identifying drug product candidates that can be advanced into the clinic.

- Presented three posters highlighting the Company's clinical development and pipeline progress at the Society for Immunotherapy of Cancer's 35th Anniversary Annual Meeting (SITC 2020). The posters included a clinical update on CUE-101, the lead drug candidate from the IL-2 based CUE-100 series and data supporting the potential of the Immuno-STAT platform to selectively engage and modulate targeted T cells within the body in a manner that can address a broad range of indications.

Cue Biopharma, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except per share information)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
Collaboration revenue	$ 475	$ 1,049	$ 3,154	$ 3,458
Operating expenses:				
General and administrative	3,446	3,100	14,651	12,740
Research and development	8,003	6,965	33,546	27,487
Total operating expenses	11,449	10,065	48,197	40,227
Loss from operations	(10,974)	(9,016)	(45,043)	(36,769)
Other income:				
Interest income	84	110	544	419
Other income / (expense) net	(6)	(12)	(80)	64
Loss before income taxes	$ (10,896)	$ (8,918)	$ (44,579)	$ (36,286)
Provision for income taxes	(206)	-	(206)	(412)
Net loss	$ (11,102)	$ (8,918)	$ (44,785)	$ (36,698)
Net loss per common share – basic and diluted	$ (0.37)	$ (0.37)	$ (1.56)	$ (1.66)

Weighted average common shares outstanding – basic and diluted	30,283,249	24,146,606	28,688,625	22,041,792

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

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 74,866	$ 44,290
Marketable securities	10,003	15,120
Total current assets	87,527	61,025
Working Capital	71,211	49,370
Total assets	99,534	71,605
Total Stockholders' equity	78,911	54,584

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 the design and clinical development of protein biologics, immunology and immuno-oncology treatments.

For more information, visit https://www.cuebiopharma.com and follow us on Twitter https://twitter.com/CueBiopharma.

Cautionary Note Regarding 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 development plans for CUE-101; the expected timing of the Phase 1b monotherapy expansion segment of the clinical trial of CUE-101; the company's plans to launch a neo-adjuvant study in newly diagnosed patients in 2021; the company's belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells; the anticipated results of the company's drug development efforts, including study results; and the company's expectations regarding regulatory developments and expected future operating results. 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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