Cue Biopharma Announces Strategic Prioritization of Autoimmune Programs Enabling Optimization of Workforce and Reduction of Capital Requirements

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Prioritizing autoimmune programs aims to focus upon near-term and intermediate value creation potential, while retaining oncology programs as promising clinical data continues to mature

- Company anticipates annualized capital and workforce requirements to be reduced by approximately 25 percent

BOSTON, July 25, 2024 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of therapeutic biologics to selectively engage and modulate disease-specific T cells, today announced the strategic prioritization of its autoimmune programs and organizational restructuring to strengthen operational efficiencies while enabling its encouraging oncology survival data to continue to mature.

"We have made substantial progress advancing the development of our autoimmune program CUE-401 through our partnership with Ono Pharmaceutical, Co., Ltd. and demonstrable preclinical progress advancing CUE-501, our program for depleting autoreactive B cells," said Daniel Passeri, chief executive officer of Cue Biopharma. "I believe each of these autoimmune programs has the potential to address multiple diseases and create near-term and intermediate value creation opportunities. While we plan to focus our resources on our novel autoimmune programs, we intend to preserve the potential value of our clinical oncology programs by retaining requisite clinical capabilities to enable maturation of clinical survival data in the current ongoing Phase 1 trials of CUE-101 and CUE-102. As such, we are actively pursuing third party support through partnerships and collaborations to further develop these programs. We believe the strategic measures we are taking will strengthen operational efficiencies and extend our capital runway."

Through strategic realignment and prioritizing autoimmune programs, along with associated organizational restructuring, Cue Biopharma expects to reduce its fiscal year 2025 operating expenses by approximately 25%, to a projected annual cash burn, based upon current assumptions, of approximately $30 million. Cue Biopharma continues to pursue additional partnership support to further improve operational efficiencies and decrease capital requirements.

To achieve its strategic objectives, Cue Biopharma has realigned its workforce requirements resulting in an approximately 25% reduction of staff across research, development and general and administrative resources. This workforce realignment along with the implementation of focused operational efficiencies is expected to extend the company's cash runway into mid-year 2025.

About CUE-401
CUE-401, partnered with Ono Pharmaceutical Co., Ltd., is a preclinical, bispecific fusion protein designed to induce and expand regulatory T cells (Tregs) through the delivery of transforming growth factor beta (TGF-β) and interleukin 2 (IL-2) with therapeutic potential across a range of T-cell mediated autoimmune and inflammatory diseases.

About CUE-501
CUE-501 is a bispecific designed to selectively harness the protective anti-viral T cell repertoire (virus-specific T cells, or VSTs) and redirect them to target and deplete B cells. Deploying a biologic to selectively redirect "killer" T cells, while avoiding the systemic engagement and activation of all T cells, to accomplish T cell-mediated B cell depletion addresses the important mechanism of autoimmune diseases and may offer significant advantages over current cell therapy-based strategies and bispecifics.

About the CUE-100 Series
The CUE-100 series consists of Fc-fusion biologics that present two signals to T cells. Signal #1 is a tumor-specific peptide linked to a major histocompatibility complex (pMHC) to enable selectivity and specificity. Signal #2 is a rationally engineered interleukin 2 (IL-2) molecule to trigger T cell activation. These singular biologics are anticipated to selectively target, activate and expand a robust repertoire of tumor-specific T cells directly in the patient's body. The binding affinity of IL-2 for its receptor has been deliberately attenuated to achieve preferential selective activation of tumor-specific effector T cells while reducing the potential for effects on regulatory T cells (Tregs) or broad systemic activation, potentially mitigating the dose-limiting toxicities associated with current IL-2-based therapies.

About CUE-101 and the Phase 1 Trial
CUE-101 is Cue Biopharma's lead clinical drug candidate from the CUE-100 series of interleukin 2 (IL-2)-based biologics. It is designed to activate and expand HPV16 tumor-specific T cells by presenting the HPV E7 protein to the HPV-specific T cell receptor. CUE-101 is currently being evaluated in a fully enrolled Phase 1 open label, dose escalation and expansion study, for the treatment of HPV16+ driven recurrent/metastatic head and neck squamous cell carcinoma in second line (2L) and beyond

patients as a monotherapy, and as a first line (1L) therapy in combination with pembrolizumab (KEYTRUDA®).

About CUE-102 and the Phase 1 Trial
CUE-102 is Cue Biopharma's second lead clinical drug candidate from the CUE-100 series of interleukin 2 (IL-2)-based biologics. It is designed to activate and expand Wilms' Tumor 1 (WT1)-specific T cells by presenting the WT1 peptide to the WT1- specific T cell receptor. WT1 is a well-recognized onco-fetal protein known to be over-expressed in a number of cancers, including solid tumors and hematologic malignancies. CUE-102 is being evaluated in a Phase 1 open label, two-part dose escalation and expansion study, for patients with late-stage colorectal, gastric/gastroesophageal junction, pancreatic and ovarian cancers that express WT1.

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body. The company's proprietary platform, Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* and biologics are designed to harness the curative potential of the body's intrinsic immune system through the selective modulation of disease-specific T cells without the adverse effects of broad systemic immune modulation.

Headquartered in Boston, Massachusetts, we are 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 please visit www.cuebiopharma.com and follow us on X and LinkedIn.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, those regarding: the company's belief regarding the potential benefits and applications of its drug candidates and programs; the near-term and intermediate value creation potential of its autoimmune programs; the company's intention to preserve the value of its oncology programs; the company's business strategies, plans and prospects, including those related to the prioritization of CUE-401 and CUE-501, partnering opportunities and the potential benefits of the company's program prioritization and realignment and workforce reduction on its burn rate; and the company's projections regarding its annualized capital requirements, cash burn rate, cash burn rate reductions, 2025 cash burn rate, workforce reductions and cash runway. 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," "promise" 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 ability to shift its focus to its autoimmune assets and achieve the cost savings that it is projecting; 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 or clinical trials or the company's ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of its product candidates; serious and unexpected drug-related side effects or other safety issues experienced by participants in clinical trials; 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 possible effects on the company's operations and 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 and ability to continue as a going concern; 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 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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