Cue Biopharma Doses First Patient in Phase 1 Study of CUE-102 for Wilms' Tumor 1 (WT1) - expressing cancers

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BOSTON, Aug. 22, 2022 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of injectable biologics to selectively engage and modulate tumor-specific T cells directly within the patient's body, announced today that it has dosed the first patient in a Phase 1 dose escalation study evaluating CUE-102, its second clinical drug candidate from the CUE-100 series of interleukin 2 (IL-2)-based biologics, as a monotherapy for the treatment of patients with Wilms' Tumor 1 (WT1)-positive recurrent/metastatic cancers. The study will initially focus on colorectal, gastric, pancreatic, and ovarian cancers.

"Initiating this Phase 1 clinical study of CUE-102 at a starting dose of 1mg/kg, a clinically active dose in our Phase 1 CUE-101 clinical trial for HPV+ head and neck cancer, is an important step forward in demonstrating the modularity of our Immuno-STAT™ platform and the broader clinical potential of our CUE-100 series of biologics," said Dan Passeri, chief executive officer of Cue Biopharma. "We believe, given the preservation of the core molecular framework between CUE-102 and CUE-101 with the primary exception of the tumor-specific epitope, initiating the dose escalation trial at 1 mg/kg will result in reduced time and cost to evaluate tolerability at therapeutically active doses."

Ken Pienta, M.D., acting chief medical officer of Cue Biopharma, added, "CUE-102 has the potential to activate the patient's immune system against numerous WT1-expressing cancers, including solid tumors and hematologic malignancies, and has demonstrated selective and significant activation of WT1-specific T cells in preclinical studies. We believe that CUE-102 can play an important role in changing the treatment landscape for patients with WT1-positive cancers, by potentially delivering higher efficacy and lower toxicities than current available treatments."

WT1 is a well-recognized onco-fetal protein that is known to be over-expressed in several cancers, including solid tumors and hematologic malignancies such as gastric, glioblastoma, pancreatic, ovarian, endometrial, breast, lung, colorectal and acute myeloid leukemia (AML). Patients with WT1-expressing cancers, and those with recurrent metastatic disease, represent an important unmet clinical need and underscore the opportunity for this promising new therapeutic.

About the CUE-102 Clinical Trial
The trial (NCT05360680) is a multi-center, open-label, Phase 1 dose escalation and expansion study evaluating the safety, tolerability, anti-tumor activity, and immunogenicity of CUE-102 in HLA-A*0201 positive patients with WT1-positive recurrent/metastatic cancers who have failed conventional therapies. The study is designed to enroll approximately 50 patients.

About CUE-102
Leveraging the Immuno-STAT ™*(Selective Targeting and Alteration of T cells)* platform of targeted interleukin 2 (IL-2) therapies and the ongoing development of the CUE-100 series including CUE-102 being developed as a novel therapeutic fusion protein to selectively activate tumor antigen-specific T cells to treat Wilms' Tumor 1 (WT1)-expressing cancers. CUE-102 consists of two human leukocyte antigen (HLA) molecules presenting a WT1 peptide, four affinity-attenuated IL-2 molecules, and an effector attenuated human immunoglobulin G (IgG1) Fc domain. WT1 is a well-recognized onco-fetal protein known to be over-expressed in several cancers, including solid tumors and hematologic malignancies.

About the CUE-100 Series
The CUE-100 series consists of Fc-fusion biologics that incorporate peptide-MHC (pMHC) molecules along with rationally engineered IL-2 molecules. This singular biologic is 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 Immuno-STAT
The company's Immuno-STAT ™ *(Selective Targeting and Alteration of T cells)* platform biologics are designed for targeted modulation of disease-associated T cells in the areas of immuno-oncology and autoimmune disease. Each of our biologic drugs is designed using our proprietary scaffold comprising: 1) a peptide-major histocompatibility complex (pMHC) to provide selectivity through interaction with the T cell receptor (TCR), and 2) a unique co-stimulatory signaling molecule to modulate the activity of the target T cells.

The simultaneous engagement of co-regulatory molecules and pMHC binding mimics the signals delivered by antigen presenting cells (APCs) to T cells during a natural immune response. This design enables Immuno-STAT biologics to engage with the T cell population of interest, resulting in selective T cell modulation. Because our drug candidates are delivered directly in the patient's body (*in vivo*), they are fundamentally different from other T cell therapeutic approaches that require the patients' T cells to be extracted, modified outside the body (*ex vivo*) and reinfused.

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate tumor-specific T cells directly within the patient's body to transform the treatment of cancer. The company's proprietary platform, Immuno-STAT ™*(Selective Targeting and Alteration of T cells)* is designed to harness the body's intrinsic immune system without the need for ex vivo manipulation.

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 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.

Investor Contact
Marie Campinell
Senior Director, Corporate Communications
Cue Biopharma, Inc.
mcampinell@cuebio.com

Media Contact
Maya Romanchuk
LifeSci Communications
mromanchuk@lifescicomms.com

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