Cue Biopharma Receives FDA Acceptance of Investigational New Drug (IND) Application for CUE-102 in Wilms' Tumor 1 (WT1) - expressing cancers

May 11, 2022

- *Company to initiate Phase 1 dose escalation and expansion trial for the treatment of Wilms' Tumor 1 (WT1) positive recurrent/metastatic cancers*
- *Starting dose of 1 mg/kg expected to reduce time and cost of dose escalation phase of trial, supporting development efficiency of CUE-100 series platform*

BOSTON, May 11, 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 targeted T cells directly within the patient's body, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application for the evaluation of CUE-102, its second interleukin 2 (IL-2)-based CUE-100 series biologic, in a dose escalation and expansion monotherapy Phase 1 trial, which will have a starting dose of 1 mg/kg for the treatment of Wilms' Tumor 1 (WT1)-positive recurrent/metastatic cancers, with initial focus on gastric, pancreatic, ovarian and colon cancers.

CUE-102 supports the modularity of the IL-2 based CUE-100 series as the core biologic framework is largely conserved with the primary difference being the incorporation of the WT1 T cell epitope. The IND acceptance allowing the dose escalation trial to begin dosing at 1 mg/kg was supported by the safety and tolerability data from the CUE-101 trial. CUE-101, the first biologic from the CUE-100 series, had a starting dose of 0.06 mg/kg and required approximately 9 months to dose escalate from 0.06 mg/kg to 1 mg/kg. As such, the starting dose of CUE-102 (targeting WT1 expressing cancers) may provide substantive time and cost savings for potentially demonstrating tolerability at therapeutically effective doses.

"The ability to start our dose escalation trial at 1 mg/kg, is significant as it allows us to initiate the trial at a dose level that demonstrated signs of clinical activity in our CUE-101 trial. At this dose level, we can potentially determine tolerability and therapeutically effective doses much more efficiently by truncating the dose escalation process," stated Ken Pienta, M.D., acting chief medical officer of Cue Biopharma. "We believe CUE-102 provides a significant opportunity to address a high unmet medical need in a wide variety of WT1-positive malignancies including colorectal, pancreatic and lung, and potentially offers a tolerable and more effective treatment option to patients in need. We believe CUE-102 has the potential to change the treatment landscape for WT1-positive patients and are very pleased to now begin evaluating its potential benefit in the clinic."

Anish Suri, Ph.D., president and chief scientific officer of Cue Biopharma said, "The IND acceptance of CUE-102 is a step forward in support of our strategic vision for pipeline expansion of assets emerging from our IL-2-based CUE-100 series of Immuno-STATs. Since the core framework and the IL-2 components are conserved, the clinical de-risking achieved with CUE-101 should in principle allow us to develop subsequent therapeutic molecules in a significantly expedited and cost-effective manner. To that end, we believe that FDA clearance to initiate the CUE-102 clinical trial at 1 mg/kg dose is an important step forward to the platform de-risking achieved with our current clinical candidate, CUE-101."

FDA acceptance of the IND application for CUE-102 is another important milestone for Cue Biopharma in their multi-target strategic collaboration with LG Chem Life Sciences, the life sciences division of LG Chem Ltd., to develop multiple Immuno-STAT biologics focused in the field of oncology.

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 CUE-101, CUE-102 is 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 a number of cancers, including solid tumors and hematologic malignancies.

Cue Biopharma's presentation at the 2021 Society for Immunotherapy of Cancer (SITC) Annual Meeting, demonstrating CUE-102's ability to selectively activate and expand WT1-specific T cells for the treatment of WT1-expressing cancers, can be accessed in the investor section of the Cue Biopharma website here.

About the CUE-100 Series
The CUE-100 series consists of Fc-fusion biologics that incorporate peptide-major histocompatibility complex (pMHC) molecules along with rationally engineered interleukin 2 (IL-2) molecules. 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 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 LG Chem Life Sciences
LG Chem Life Sciences is a business division within LG Chem, engaged in the development, manufacturing, as well as commercializing pharmaceutical products globally. LG Chem Life Sciences seeks to expand and make global presence by focusing on key core therapeutic areas of Immunology, Oncology, and Metabolic Diseases (specifically, diabetes and related metabolic diseases). To achieve such, its strategy is to actively pursue global collaboration encompassing from asset-centric to strategic investment and collaboration. LG Chem Life Sciences Innovation Center: innovation.lgchem.com

About Cue Biopharma
Cue Biopharma, a clinical-stage biopharmaceutical company, is developing a novel class of injectable biologics to selectively engage and modulate targeted T cells within the patient's body to transform the treatment of cancer, infectious disease and autoimmune disease. 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 belief that the Immuno-STAT platform stimulates targeted immune modulation through the selective engagement of disease-relevant T cells; the Company's plans and expectations related to the clinical development of CUE-102 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.