

# Cue Biopharma and LG Chem Life Sciences Announce Development Milestone in Immuno-STAT Biologics Collaboration for CUE-102

January 5, 2022

- Selective activation and expansion of Wilms' Tumor 1 (WT1)-specific cytotoxic CD8+ T cells in preclinical models supports the potential for clinical activity treating WT1-expressing cancers
- Further advancement of CUE-102 enhances pipeline development and demonstrates modularity of the Immuno-STAT ™ platform for addressing a myriad of cancer antigens

CAMBRIDGE, Mass., Jan. 05, 2022 (GLOBE NEWSWIRE) -- <u>Cue Biopharma, Inc.</u> (Nasdaq: CUE), a clinical-stage biopharmaceutical company engineering a novel class of injectable biologics to selectively engage and modulate targeted T cells directly within the patient's body, along with LG Chem Life Sciences, announced today that a key milestone in the selection of a clinical product candidate has been reached in their collaboration for CUE-102, an Immuno-STAT<sup>™</sup> biologic, jointly developed to selectively target WT1-expressing cancers. The milestone represents significant progress for the CUE-102 program and an important achievement in generating promising preclinical activity and data to be shared with the FDA as part of an investigational New Drug (IND) filing that is planned for the first quarter of 2022. Under the terms of the collaboration agreement, Cue Biopharma will receive a \$3 million milestone payment from LG Chem Life Sciences, the life sciences division of LG Chem Ltd.

"We are highly encouraged with the progress made in our collaboration with LG Chem, our partner and collaborator for CUE-101 and CUE-102 in certain Asia countries, and pleased to be advancing CUE-102 for a planned IND submission this year," said Daniel Passeri, chief executive officer of Cue Biopharma. "This milestone reflects ongoing progress for CUE-102, our second program from the IL-2 based CUE-100 series, and we believe provides a significant opportunity to address a high unmet need in a wide range of solid tumors and hematologic WT1-positive malignancies. The CUE-102 preclinical data continues to support and bolster the versatility and modularity of our CUE-100 series biologics and the Immuno-STAT platform, and we look forward to executing on our goal to advance this drug candidate into the clinic for patients in need."

Dr. Jeewoong Son, president of LG Chem Life Sciences added, "This significant milestone for CUE-102 underscores the spirit of the partnership and collaboration for advancing our shared vision with Cue Biopharma. We are very pleased and encouraged by the clinical data reported from the CUE-101 program and believe these data support the potential for CUE-102 to provide a significant therapeutic advancement for patients with WT1-expressing cancers."

Cue Biopharma presented preclinical data on CUE-102 and interim clinical data on CUE-101, its lead oncology asset, at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting in November 2021.

# About Immuno-STAT

The company's Immuno-STAT  $^{TM}$  (Selective Targeting and Alteration of T cells) platform biologics are designed for targeted modulation of diseaseassociated 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 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 CUE-102

Leveraging the Immuno-STAT <sup>TM</sup> (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.

## 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 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 disease and autoimmune disease. The company's proprietary Immuno-STAT TM (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 forwardlooking statements include, but are not limited to, those regarding: the company's plans to submit an IND for CUE-102; 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 forwardlooking 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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