Cue Biopharma Enters into a Strategic Collaboration and Option Agreement with Ono Pharmaceutical for CUE-401

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BOSTON, Feb. 22, 2023 (GLOBE NEWSWIRE) -- Cue Biopharma, Inc. (Nasdaq: CUE), a clinical-stage biopharmaceutical company developing a novel class of injectable biologics to selectively engage and modulate disease-specific T cells directly within the patient's body, announced today a collaboration and option agreement with Ono Pharmaceutical Co., Ltd. ("Ono"), for CUE-401, a bispecific protein designed to induce and expand regulatory T cells (Tregs) for the treatment of autoimmune and inflammatory diseases.

The strategic collaboration with Ono is an important advancement in Cue Biopharma's corporate development plan to seek third party support to further develop its CUE-400 series and provides dedicated resources and capabilities to help advance CUE-401 toward the clinic. In preclinical studies, CUE-401 has demonstrated induction and expansion of Tregs, with the potential to address a broad range of autoimmune and inflammatory diseases.

Under the terms of the agreement, Ono will pay Cue Biopharma an upfront payment and fully fund all research activities related to CUE-401 through a specified option period. During this option period Cue Biopharma will be responsible for the research and development of CUE-401. Upon Ono's exercise of its option to license CUE-401, Cue Biopharma will receive an option exercise payment and be eligible for development and commercial milestone payments up to an aggregate of approximately $220 million, as well as tiered royalties on sales. Upon any such exercise, Ono will receive worldwide rights to develop and commercialize CUE-401, with Cue Biopharma retaining a 50% co-development and co-commercialization right in the United States.

"This strategic collaboration with Ono Pharmaceutical, a leading Japanese pharmaceutical company with a track record of scientific innovation, is a significant accomplishment for Cue Biopharma, as it allows us to further develop this promising biologic through the support of a strategic partner," stated Daniel Passeri, chief executive officer of Cue Biopharma. "Through this important partnership we have secured resources and capabilities necessary to help advance CUE-401 towards the clinic, while preserving potential value to our shareholders through a 50:50 collaboration right for the U.S. market."

"We appreciate Cue Biopharma's proprietary platform, protein engineering abilities, as an emerging new therapeutic modality and are thrilled to work with Cue Biopharma's biologics team through this collaboration agreement." said Toichi Takino, Senior Executive Officer/Executive Director, Discovery & Research of Ono Pharmaceutical. "We hope to add CUE-401 into our portfolio to help patients suffering from autoimmune and inflammatory diseases."

About CUE-401
CUE-401 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 Ono Pharmaceutical Co., Ltd.
Ono Pharmaceutical Co., Ltd., headquartered in Osaka, is an R&D-oriented pharmaceutical company committed to creating innovative medicines in specific areas. Ono focuses its research on oncology, immunology, neurology and specialty research with high medical needs as priority areas for discovery and development of innovative medicines. For further information, please visit the company's website at https://www.ono-pharma.com/en.

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 body's intrinsic immune system as T cell engagers without the need for ex vivo manipulation or 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 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 potential benefits and results that may be achieved through the collaboration with Ono; 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.

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