



Cue Biopharma Announces Presentation Highlighting Immuno-STAT Platform and CUE-101 at the 2019 Keystone Symposia Conference

January 16, 2019

Data Highlights the Potential of the CUE-100 Series to Selectively Deliver IL-2 to Tumor-relevant T cells while Mitigating the Risk Associated with Systemic IL-2 Activation

CAMBRIDGE, Mass., Jan. 16, 2019 (GLOBE NEWSWIRE) -- [Cue Biopharma](#), Inc., (NASDAQ: CUE) an innovative immunotherapy company developing a novel, proprietary class of biologics engineered to selectively modulate the human immune system to treat cancer, autoimmune and chronic infectious diseases, announced today a poster presentation featuring pre-clinical data on its lead candidate CUE-101, an Immuno-STAT™ (Selective Targeting and Alteration of T cells) Biologic being developed for the treatment of HPV-associated cancers, at the Keystone Symposia Conference, January 20-24 in Vancouver, British Columbia.

Details for the poster presentation are as follows:

Title: CUE-101, a novel Fc fusion for selective targeting and expansion of anti-tumor T cells for treatment of HPV-driven malignancies

Poster Number: 1035

Poster Session: Poster Session 1, Monday, January 21, 2019

Location: Fairmont Hotel Vancouver

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"Cue Biopharma is pleased to present important data highlighting the potential of our Immuno-STAT platform and lead candidate CUE-101 to enhance anti-tumor immunity in patients with HPV16-driven malignancies," said Anish Suri, Ph.D., Senior Vice President and Chief Scientific Officer of Cue Biopharma. "CUE-101, as representative of our CUE-100 series, demonstrated selective binding, preferential activation and in vitro expansion of antigen-specific T cells – even with transient exposure to the drug. Furthermore, direct effects of CUE-101 versus wild type IL-2 on human primary blood mononuclear cells (PBMCs) demonstrated significant reduction of non-specific cytokine production and cell-surface activation markers. We believe these early data support a potentially favorable safety and efficacy profile for the CUE-100 series that contains affinity attenuated IL-2 to favor tumor-specific T cell engagement over systemic IL-2 that interacts broadly with all T cells and other immune cells."

"The data to be presented demonstrates our ability to protein engineer a selective T cell modulatory biologic providing the benefits of selective IL-2 activity while eliminating or ameliorating the unwanted collateral effects of non-selective, global stimulators," said Dan Passeri, M.Sc., J.D., President and CEO of Cue Biopharma. "Through protein engineering, we have developed an IL-2 framework forming the basis of our CUE-100 series, which holds tremendous promise for addressing a myriad of cancers by changing the targeting epitope, such as HPV for CUE-101 and WT1 for CUE-102."

The poster also shows that in this study, CUE-101 induced inhibition of tumor growth in vivo both as a monotherapy, and in combination with a PD-1 inhibitor.

The poster will be available in the Events and Presentations section of the Investor page at www.cuebio.com following the presentation at the Keystone Symposia Conference.

Cue Biopharma previously presented foundational [data](#) on CUE-101 and the Immuno-STAT platform at the Society for Immunotherapy of Cancer's (SITC) 33rd Annual Meeting in November.

About CUE-100 Framework

Drug candidates developed within the CUE-100 framework selectively stimulate the interleukin 2 (IL-2) receptor, a potent activator of the pathway critical to the growth, expansion and survival of T cells. We have engineered the framework to activate specific T cell populations through peptide-MHC complex (pMHC) targeting of T cell receptors (TCRs) and selective deployment of the IL-2 signal. The IL-2 has been attenuated to achieve preferential activation of tumor specific T-cells without systemic activation, potentially mitigating the dose-limiting toxicities associated with current IL-2-based therapies.

The lead program from the CUE-100 framework, CUE-101, contains IL-2 and a pMHC composed of HLA-A*02:01 complexed with a dominant peptide derived from the human papilloma virus E7 protein (HPV-E7). It is a fusion protein biologic designed to target and activate antigen-specific T cells to fight HPV-driven cancers.

About Immuno-STATs

Immuno-STAT Biologics are designed for targeted modulation of disease-associated T cells in the areas of immuno-oncology, autoimmune and chronic infectious disease. Each of our biologic drugs is designed using our proprietary scaffold comprising: 1) a peptide-MHC complex (pMHC) to provide selectivity through the pMHC T-cell receptor (TCR) interaction, and 2) a unique co-stimulatory signaling molecule to modulate the activity of the target T cells.

The simultaneous engagement of co-stimulatory 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 exclusively, resulting in highly targeted T cell modulation. Because our drugs are delivered in vivo, they are fundamentally different from other T cell therapeutic approaches such as Adoptive Cell Therapy (ACT), which require the patients' T cells to be extracted, then stimulated and expanded outside the body.

(ex vivo) and reinfused in an activated state. At Cue Biopharma, we are working to develop drugs that will represent a potent pharmaceutical analog to the ex vivo approach deployed by current cellular therapies. Furthermore, we believe the pharmacological effect in the patients can be more precisely controlled via an administered therapeutic.

About Cue Biopharma

Cue Biopharma is an innovative immunotherapy company developing a novel, proprietary class of biologics engineered to selectively modulate the human immune system to treat a broad range of cancers, autoimmune and chronic infectious diseases. We design biologics to engage and modulate the activity of disease-associated T cells in the patient's body, with the goal of offering significant therapeutic benefits while potentially minimizing or eliminating unwanted side effects.

We believe our selective biologics allow us to target antigen-specific T cell populations in a variety of indications using a peptide – MHC complex for delivering T cell modulating effectors, such as IL-2. Once a biologic has been optimized, our approach offers the potential for readily exchanging peptides to target different T cell populations and indications using previously-validated drug frameworks developed from the Immuno-STAT™ (Selective Targeting and Alteration of T cells) platform. This flexibility could truncate the drug selection and development process, moving effective therapeutics from discovery to clinical validation more rapidly and cost-efficiently than current industry standard timelines and costs.

Headquartered in Cambridge, MA, we are led by an experienced management team and scientific and clinical advisory board (SAB/CAB) with deep expertise in the design and clinical development of protein biologics, immunology and immuno-oncology.

For more information, visit www.cuebio.com.

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. Forward-looking statements, which are based on certain assumptions and describe our 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. All statements other than statements of historical facts included in this press release regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding anticipated results of our drug development efforts, including study results, our expectations regarding regulatory developments and expected future operating results. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, our limited operating history, limited cash and a history of losses; our ability to achieve profitability; our ability to secure required U.S. Food and Drug Administration (“FDA”) or other governmental approvals for our product candidates and the breadth of any approved indication; negative or inconclusive results from our clinical studies or serious and unexpected drug-related side effects or other safety issues experienced by participants in our clinical trials; delays and changes in regulatory requirements, policy and guidelines including potential delays in submitting required regulatory applications to the FDA; our reliance on licensors, collaborations and strategic alliances; our ability to obtain adequate financing to fund our business operations in the future; 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 our 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 us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake 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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