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Immune Design Announces Positive Topline Data From Three Phase 1 Clinical Trials of Immuno-Oncology Agents

SEATTLE and SAN FRANCISCO, March 31, 2015 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on cancer, reported today that analyses of data from three ongoing Phase 1 studies support continued development of its two primary product candidates, CMB305 and G100.

CMB305 and G100 represent Immune Design's two distinct approaches to fighting cancer via the *in vivo* induction and/or expansion of anti-tumor CD8 T cells. CMB305 belongs within the Specific Antigen approach and is a "first-in-class" prime-boost therapy containing two potentially synergistic agents, LV305 and G305. CMB305 targets the tumor antigen, NY-ESO-1, which is expressed in a wide range of tumors. In contrast, G100 belongs within the Endogenous Antigen, or intra-tumoral immune activation, approach and relies on activating an anti-tumor immune response by its administration directly into the tumor. G100 is expected to directly activate dendritic and other antigen presenting cells near the tumor, which may enhance the function of pre-existing cytotoxic T lymphocytes (CTLs) and create an immune response against neo-antigens. Both are designed to work *in vivo* and provide a potential "off the shelf" therapy, in contrast to other, *ex vivo* T cell approaches.

CMB305

CMB305's "prime" and "boost" components, LV305 and G305, were well tolerated and demonstrated specific and selective immunogenicity in two parallel Phase 1 studies to meet the company's guidelines to progress CMB305 into development:

- After reviewing the safety data from each of the two studies, the DSMBs for each study voted that each agent was safe without dose-limiting toxicities;
- A significant subset of LV305 treated patients had NY-ESO-1-specific CD8 T cell responses that were generated or increased after therapy;
- A significant subset of G305 patients had a combination of NY-ESO-1-specific CD4 T cells and antibody responses that were generated or increased after therapy; and
- Clinical benefit in the form of stable disease was observed in a number of patients.

G100

- The ongoing safety analysis demonstrates an acceptable profile alone or in combination with local radiation; and
- In addition to the initial complete response previous reported, we have observed additional evidence of clinical efficacy.

Abstracts for each of these three Phase 1 studies have been submitted for presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting (May 29-June 2, 2015). If afforded the opportunity to present, it is the company's intent to work with the Principal Investigator for each product candidate to present a more complete data set at the Conference.

"We are very encouraged by the data produced thus far in all three Phase 1 studies," said Carlos Paya, M.D., Ph.D, President and Chief Executive Officer of Immune Design. "The data from the dose escalation Phase 1 studies of LV305 and G305 met our internal requirements for demonstrating that each of these two 'building blocks' of CMB305 selectively activates different arms of the immune response against NY-ESO-1, thus providing a strong rationale for their combination into the unique 'prime-boost' approach intended to generate *in vivo* anti-NY-ESO-1 CTLs in our recently announced Phase 1b trial of CMB305. Likewise, the continued evidence of the therapeutic effects of G100 alone or in combination with radiation further supports the development of G100 under the 'intra-tumoral immune activation' approach."

About CMB305

CMB305 is an immuno-oncology product candidate combining two potentially synergistic agents, LV305 and G305, and is part of Immune Design's Specific Antigen approach to treating cancer and is a product of the ZVex^{TM} discovery platform. This approach is designed to deliver specific tumor antigens in RNA form directly to cancer patients' dendritic cells using a cutting-edge gene delivery vector specific for a subset of skin dendritic cells. CMB305 is designed to target NY-ESO-1-expressing cancers and is intended to be an "off-the shelf" therapy that does not require patient-specific manufacturing or *ex vivo* manipulation of patient samples. The NY-ESO-1 protein is provided by the Ludwig Institute for Cancer Research. CMB305 is currently being evaluated in a Phase 1b open label, dose escalation, multi-center trial designed to evaluate the safety and tolerability, immunogenicity, and preliminary clinical efficacy of CMB305 in patients with any of four solid tumor types that are locally advanced, relapsed or metastatic and express NY-ESO-1.

About G100

G100 is intended for intra-tumoral injection and is part of Immune Design's intra-tumoral Immune Activation/Endogenous Antigen approach to treating cancer, which leverages an intra-tumoral activation of dendritic cells in the tumor microenvironment to potentially create a robust local and systemic anti-tumor immune response. G100 is a product of the company's GLAAS^{TM} platform, and is currently being studied in two separate pilot Phase 1 studies: one in patients with Merkel Cell Carcinoma, or MCC; and one via an investigator-sponsored trial in sarcoma patients in combination with local radiation.

About Immune Design

Immune Design is a clinical-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease. The company's technologies are engineered to activate the immune system's natural ability to generate and/or expand antigen-specific cytotoxic T cells, while enhancing other immune effectors, to fight cancer and other chronic diseases. CMB305 and G100, the two-pronged focus of Immune Design's ongoing immuno-oncology clinical programs, are the product of its two synergistic discovery platforms: ZVex and GLAAS, the fundamental technologies of which were licensed from the California Institute of Technology and the Infectious Disease Research Institute (IDRI), respectively. Immune Design has offices in Seattle and South San Francisco. For more information, visit www.immunedesign.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Immune Design's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the clinical development of Immune Design's product candidates. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of Immune Design's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Other factors that may cause Immune Design's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Immune Design's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Immune Design assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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