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Immune Design Announces Treatment of Patients With CMB305 Investigational Immuno-Oncology Agent

Prime-Boost *in vivo* T cell active immunotherapy

SEATTLE and SOUTH SAN FRANCISCO, Calif., March 26, 2015 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on cancer, today announced the dosing of patients in a Phase 1b clinical trial of CMB305, a "prime-boost" immuno-oncology product candidate generated from the company's ZVex™ and GLAAS™ platforms. CMB305 is the first product candidate of Immune Design's Specific Antigen approach, which is one of the company's two distinct approaches to fighting cancer.

CMB305 is a novel combination product that involves the sequential dosing of two complementary agents, LV305 and G305, and is designed to synergistically induce anti-tumor cytotoxic T lymphocytes (CTLs) to target tumors that express NY-ESO-1, a tumor antigen found in a broad set of tumors.

"CMB305's prime-boost approach leverages the activation of two separate arms of the patient's immune system, that when combined under this novel approach, are designed to induce a strong and long lasting anti-tumor CD8 T cell response, as well as activate other complementary immune effectors that may help to fight cancer," said Carlos V. Paya, MD, PhD, chief executive officer of Immune Design.

The Phase 1b open label, multi-center trial ([NCT02387125](#)) is designed to evaluate the safety and tolerability, immunogenicity, and preliminary clinical efficacy of CMB305 in patients with locally advanced, relapsed or metastatic solid cancers expressing NY-ESO-1. The study is divided into two parts. Part 1 is a dose escalation study in up to 12 patients. Part 2 will be an expansion study of the optimal dose in approximately 27 patients.

About CMB305

CMB305 is an immuno-oncology product candidate combining two potentially synergistic agents. The first agent, LV305, is a hybrid vector from the ZVex platform that specifically targets dendritic cells (DCs) *in vivo* and delivers the RNA for NY-ESO-1, enabling the DCs to express the entire tumor antigen to potentially induce a diverse set of CTLs. G305 is the second agent and is designed to boost the CTL response via the induction of antigen-specific CD4 "helper" T cells. G305 consists of recombinant NY-ESO-1 protein formulated with a proprietary synthetic small molecule called glucopyranosyl lipid A (GLA), the novel TLR4 agonist at the core of the GLAAS platform. CMB305 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.

For Patients

The CMB305 trial is being conducted at a number of leading cancer research organizations. Information about this study, including additional eligibility criteria and contact information, can be found on [clinicaltrials.gov](#).

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 foci of Immune Design's on-going 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 expected mechanism and results of CMB-305 and its potential impact on cancer treatment. 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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