# IMMUNE HDESIGN

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# Immune Design Presents Preclinical Data on G100 and ZVex(TM) in Combination With Check Point Inhibitors at the 2015 Society for Immunotherapy of Cancer Annual Meeting

## Demonstrates Potential of "Prime-Pull" Immunotherapy Approach

SEATTLE and SOUTH SAN FRANCISCO, Calif., Nov. 3, 2015 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on oncology, today announced new preclinical data showing that a dendritic-cell targeting lentiviral vector from its ZVex<sup>™</sup> immunotherapy platform administered with G100, which contains a potent synthetic TLR4 agonist, synergize with immune check point inhibitors and demonstrate potent local and systemic anti-tumor

activity in cancer models. These data are being presented at the 30<sup>th</sup> Annual Meeting of the Society for Immunotherapy of Cancer (SITC) Conference, National Harbor, Maryland, November 4-8, 2015.

"These findings further illustrate the potential of ZVex-based product candidates and G100 to play an important role in the emerging field of cancer immunotherapy, especially in potential combination therapies with immune checkpoint inhibitors," said Jan ter Meulen, MD, PhD, Chief Scientific Officer at Immune Design. "Mechanistically, it is generally believed that the generation of tumor-specific CD8 T-cells can improve the clinical efficacy of checkpoint inhibitors, especially in patients with insufficient T-cell responses. These preclinical data provide a strong rationale for our ongoing and planned clinical trials which combine LV305, CMB305 and G100, agents from our ZVex and GLAAS discovery platforms, with KEYTRUDA and Atezolizumab."

In the presentations, Immune Design scientists present data showing that in the murine B16 melanoma model, intratumoral injection of G100 improves the trafficking of ZVex-induced antigen-specific CD8 T-cells into tumors and induces systemic antitumor immunity mediated by antigen spreading. This discovery that Immune Design's two platforms appear to "pull" T cells (G100) that were "primed" (ZVex agent) into the tumor potentially opens up new possibilities of enhancing the immunotherapy of solid tumors by changing the tumor microenvironment. In addition, combining G100 or a ZVex agent with both anti-PD1 and anti-PDL1 antibodies demonstrated increased efficacy in this experiment. The presentations are entitled "Intratumoral Injections of G100 (synthetic TLR4 agonist) Increases Trafficking of Lentiviral Vector-induced Antigen-specific CD8 T Cells to the Tumor Microenvironment" and "Checkpoint Inhibitors Synergize with Therapeutic Platforms, ZVex<sup>™</sup> and GLAAS<sup>™</sup> by Enhancing Lentiviral Vector-induced Tumor-specific Immunity and Adjuvant-mediated Anti-tumor Efficacy."

These abstracts will be published in the <u>Journal for ImmunoTherapy for Cancer</u> on November 4, 2015, and the posters will be posted on the <u>publications page of the Immune Design website</u> following presentation at the conference.

### About G100

G100 is a product candidate generated from the company's GLAAS<sup>TM</sup> discovery platform, and includes a specific formulation of Glucopyranosyl Lipid A (GLA), a synthetic, toll-like receptor-4 (TLR-4) agonist. G100 is part of Immune Design's intratumoral immune activation, or 'Endogenous Antigen' approach to treating cancer, which leverages the activation of dendritic cells, T cells and other immune cells in the tumor microenvironment to potentially create a robust immune response against the tumor's preexisting diverse set of antigens. Preclinical and clinical data have demonstrated the ability of G100 to activate dendritic cells in tumors and to increase antigen-dependent systemic humoral and cellular Th1 immune responses. A Phase 1 study of G100 in patients with Merkel cell carcinoma (MCC) recently completed enrollment, and Immune Design presented data at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting. In the first eight patients in MCC study, G100 had an acceptable safety profile and the combined therapy of G100 followed by radiation and/or surgery resulted in an objective response rate (ORR) of 50%. A second Phase 1 trial is planned to examine intratumoral administration of G100 with

intravenous administration of KEYTRUDA<sup>®</sup> (pembrolizumab), Merck's anti-PD-1 therapy, in patients with follicular non-Hodgkin's lymphoma receiving local radiation. In addition to an evaluation of the safety of the combination, the study will assess the response in both injected and non-injected lesions.

### About ZVex™

ZVex is Immune Design's discovery platform designed to activate and expand the immune system's natural ability to create tumor-specific cytotoxic T cells (CTLs) *in vivo*.

The ZVex delivery system uses a re-engineered virus to carry genetic information of a tumor antigen selectively to dendritic cells (DCs) in the skin. This ultimately results in the creation of CTLs designed to kill tumor cells bearing that same specific tumor antigen.

#### **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 also enhancing other immune effectors, to fight cancer and other chronic diseases. CMB305 and G100, the primary focus of Immune Design's ongoing immuno-oncology clinical programs,

are products of its two synergistic discovery platforms, ZVex<sup>TM</sup> and GLAAS<sup>TM</sup>, 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 <u>www.immunedesign.com</u>.

#### Forward Looking Statement:

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 timing of initiation, progress, scope and outcome of clinical trials for Immune Design's product candidates and the reporting of clinical data regarding 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 forwardlooking statements contained herein to reflect any change in expectations, even as new information becomes available.

CONTACT: Contact for Immune Design:

Media Contact Julie Rathbun Rathbun Communications julie@rathbuncomm.com 206.769.9219 Investor Contact Shari Annes Annes Associates sannes@annesassociates.com

650-888-0902