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Immune Design Announces Positive Topline Data From Three Phase 1 Clinical Trials of Immuno-oncology Product Candidates

New Data Support the Continued Development of Both CMB305 and G100

SEATTLE and SOUTH SAN FRANCISCO, Calif., Feb. 09, 2016 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on oncology, today reported positive topline data from three ongoing Phase 1 oncology studies that support continued development of its two primary *in vivo* immuno-oncology product candidates, CMB305 and G100.

CMB305: First-in-class Prime-boost Immunotherapy Targeting NY-ESO-1 Tumors

Data from a completed first-in-human dose-escalation study and an early subset of patients from an expansion study of CMB305 as a single agent in patients with cancers expressing the NY-ESO-1 tumor antigen revealed:

- CMB305 was safe, without dose-limiting toxicities, as reviewed by an independent data safety monitoring board (DSMB);
- A significant subset of CMB305-treated patients had NY-ESO-1-specific CD8 T cell responses that were generated or increased after therapy;
- Patients who did respond immunologically had a greater degree of antigen-specific T cell response than that previously reported in a Phase 1 study of LV305 alone, which is consistent with the intent of the prime-boost approach; and
- Preliminary clinical benefit in the form of progression-free rate (PFR) was observed in patients with soft tissue sarcoma.

LV305: Novel Vector Delivering NY-ESO-1 RNA Specifically to Dendritic Cells *in vivo* Maintains Safety and Immunogenicity with Improved Clinical Benefit Profile

Data from the expansion study following the previously-reported dose escalation study of LV305 in patients with tumors expressing NY-ESO-1 revealed:

- A consistently favorable safety profile, as reviewed by an independent DSMB;
- A consistent immune response rate; and
- An improved clinical benefit profile.

G100: Intratumoral Administration of aTLR4 Agonist Significantly Modifies the Tumor Microenvironment (TME) and Maintains Clinical Benefit

New data from the completed pilot trial of G100 with local radiation in patients with Merkel cell carcinoma revealed:

- Safety was consistent with that originally reported, demonstrating an acceptable profile alone or in combination with local radiation;
- G100 significantly altered the TME, causing inflammation and transforming tumors to a "hot" state in G100 responding patients; and
- Clinical benefit remained constant with the full patient set.

Abstracts for each of these three Phase 1 studies have been submitted for presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting (June 3-7, 2016). 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.

"The accumulating data, including this new set, clearly supports proceeding with the clinical development of our two first products, CMB305 and G100, each activating the anti-tumor immune response by targeting a predefined tumor antigen or neo-antigens, respectively," said Carlos Paya, M.D., Ph.D, President and Chief Executive Officer of Immune Design. "The initiation of randomized studies in which we are combining our two products with inhibitors of the PD-1/L1 axis through our collaborations with Genentech and Merck will provide the evidence as to how novel products that activate the immune system and aim to make tumors "hot" add or synergize with check-point inhibitors."

Additional Information on Immune Design's Distinct Immuno-oncology Approaches

About CMB305

CMB305 is an immuno-oncology product candidate that involves the sequential dosing of two active agents, LV305 and G305. LV305 is a hybrid vector from the ZVex™ discovery 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 and potentially induce a diverse set of CTLs targeting NY-ESO-1 in tumors. G305, in contrast, 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. Immune Design has conducted prior studies to establish the safety and individual immunologic activity of LV305 and G305. CMB305 is currently being evaluated in a Phase 1B trial in patients with locally advanced, relapsed or metastatic solid cancers whose tumors express NY-ESO-1 and a randomized Phase 2 trial of CMB305 combined with Genentech's investigational cancer immunotherapy, atezolizumab (anti-PD-L1), in patients with soft tissue sarcoma, pursuant to a collaboration with Genentech.

About G100

G100 is Immune Design's intratumoral Immune Activation approach to treating cancer and 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 both a local and systemic immune response against neo-antigens. G100 is a product of the company's GLAAS platform and recently completed a Phase 1 study in patients with Merkel cell carcinoma. G100 also has potential therapeutic utility in any accessible tumor and will be investigated in combination with local radiation and Merck's anti-PD-1 agent, KEYTRUDA®, in a randomized study in patients with follicular Non-Hodgkin lymphoma, pursuant to a collaboration with Merck.

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 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 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 forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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