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Immune Design Announces Start of Randomized Phase 2 Cancer Immunotherapy Combination Trial in Patients With Soft Tissue Sarcoma

Study to Evaluate Combination of Immune Design's CMB305 and Genentech's Atezolizumab

SEATTLE and SOUTH SAN FRANCISCO, Calif., Nov. 11, 2015 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on oncology, today announced the start of a randomized Phase 2 trial of CMB305, the company's "prime boost" cancer immunotherapy product candidate, combined with Genentech's investigational cancer immunotherapy, atezolizumab (MPDL3280A; anti-PD-L1) in patients with soft tissue sarcoma.

The open label trial is designed to evaluate the safety and efficacy of CMB305 in combination with atezolizumab versus atezolizumab alone in up to 80 patients with locally advanced, relapsed, or metastatic synovial sarcoma or myxoid/round-cell liposarcoma expressing the NY-ESO-1 cancer testis antigen. The trial is being conducted pursuant to a clinical collaboration with Genentech, a member of the Roche Group, which will provide atezolizumab for the trial.

CMB305 is a "prime-boost" cancer immunotherapy product designed to synergistically induce and expand *in vivo* cytotoxic T lymphocytes (CTLs) targeting NY-ESO-1 which is found in a broad set of tumors. Specifically, synovial sarcoma and myxoid/round-cell liposarcoma tend to express NY-ESO-1 broadly, which should make them good indications for clinical studies of this antigen-specific immune therapy. Atezolizumab is designed to target PD-L1 expressed on tumor cells and tumor-infiltrating immune cells, preventing it from binding to PD-1 and B7.1 on the surface of T cells. By inhibiting PD-L1, atezolizumab may enable the activation of T cells..

"This trial provides our first opportunity to validate the fundamental hypothesis that combining cutting-edge technologies designed to trigger *in vivo* anti-tumor CTLs with antagonists of the PD-1/PD-L1 axis should be additive, if not synergistic, and thus could enhance the potential therapeutic benefit to patients," said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design. "We are excited to work with leading sarcoma investigators to advance CMB305 into its first randomized Phase 2 trial and to explore the potential of these two approaches."

About CMB305

CMB305 is a cancer immunotherapy product candidate combining two potentially synergistic 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. Having established the safety and individual immunologic activity of LV305 and G305 in prior studies, Immune Design initiated a new Phase 1B study of the product candidate CMB305 earlier this year.

About Soft Tissue Sarcoma

Soft Tissue Sarcomas (STS) are malignancies that arise from the soft tissues of the body, such as tissues that connect, support and surround other body structures including muscle, fat, blood vessels, nerves, tendons and the lining of joints.[1] In the United States, nearly 12,000 people will be diagnosed and approximately 4,870 are expected to die of STS in 2015.[2] There are approximately 50 different types of STS including Liposarcomas and Synovial Sarcomas, which are subtypes affecting fat tissue and tissue around the joints, respectively.[3] Myxoid/round cell is a type of liposarcoma that accounts for approximately 30% of all liposarcoma cases.[4] Myxoid and round cell liposarcoma and synovial sarcomas have been shown to have high expression of NY-ESO-1, approximately 90% and approximately 60%, respectively.[5]

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, ZVexand 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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[4] Orpha.net. Myxoid/round cell liposarcoma.

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[5] Endo, M., et al. (April 2015). NY-ESO-1 (CTAG1B) expression in mesenchymal tumors [Abstract]. *Modern Pathology*, 28, 587-595.

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