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Immune Design Receives Orphan Drug Designation From the U.S. FDA for Complementary Components of CMB305

Designation for LV305 and G305

SEATTLE and SOUTH SAN FRANCISCO, Calif., Jan. 08, 2016 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on oncology, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for LV305 and G305 for the treatment of soft tissue sarcoma. LV305 and G305 are the complementary agents that comprise CMB305, Immune Design's "prime boost" cancer immunotherapy product candidate.

Orphan Drug Designation is granted by the FDA Office of Orphan Drug Products to products that treat rare diseases. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States. Orphan Drug Designation provides the sponsor certain benefits and incentives, including a period of marketing exclusivity for the first marketing application, if regulatory approval is received for the designated indication, potential tax credits for certain activities and waiver of certain administrative fees.

CMB305 is a cancer immunotherapy product candidate that involves the sequential dosing of 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 (MPDL3280A; anti-PD-L1) in patients with soft tissue sarcoma, pursuant to a collaboration with Genentech.

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 immunology 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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