February 22, 2017

Immune Design Receives Orphan Drug Designation for G100 Intratumoral Product Candidate

SEATTLE and SOUTH SAN FRANCISCO, Calif., Feb. 22, 2017 (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 its investigational intratumoral therapy, G100, for the treatment of follicular non-Hodgkin's lymphoma.

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.

G100 is a product candidate from Immune Design's GLAAS® discovery platform. It contains a potent synthetic small molecule toll-like receptor-4 (TLR-4) agonist, Glucopyranosyl Lipid A (GLA), and is the lead product candidate in Immune Design's Antigen Agnostic approach. It leverages the activation of both innate and adaptive immunity, including Dendritic Cells, in the tumor microenvironment to create an immune response against the tumor's preexisting diverse set of antigens. A growing set of clinical and preclinical data have demonstrated the ability of G100 to activate tumor-infiltrating lymphocytes, macrophages and dendritic cells, and promote antigen-presentation and the recruitment of T cells to the tumor. The ensuing induction of local and systemic immune responses has been shown to result in local and abscopal (shrinking of tumors outside the scope of the localized treatment) tumor control in preclinical studies. G100 was evaluated in a Phase 1 study in Merkel cell carcinoma patients and produced a 50% overall response rate per protocol and a favorable safety profile. Currently, G100 is being evaluated as both a monotherapy (with local radiation) and in combination with Merck's anti-PD-1 agent, pembrolizumab, pursuant to a clinical collaboration with Merck, in a randomized Phase 1/2 trial in patients with follicular non-Hodgkin's lymphoma.

CMB305, Immune Design's prime-boost cancer immunotherapy product candidate, has previously been designated orphan drug status for soft tissue sarcoma by the FDA, and each of the two agents comprising CMB305 also have both U.S. and European Orphan drug designation for soft tissue sarcoma.

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 foci 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 progress, scope and outcome of clinical trials for Immune Design's product candidates, the reporting of clinical data regarding Immune Design's product candidates and the timing and likelihood of regulatory filings and approvals. 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, and unexpected litigation or other disputes. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Orphan Drug Designation does not provide any assurance of regulatory

approval or expedite regulatory review. 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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