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Immune Design Announces First Patients Dosed in Phase 1 Clinical Trial of G100 Investigational Immuno-Oncology Agent

Investigator-Sponsored Trial to Evaluate Combination of G100 With Local Radiation Therapy in Patients With Sarcoma

SEATTLE and SOUTH SAN FRANCISCO, Feb. 11, 2015 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company, today announced the start of a Phase 1 clinical trial of G100 in combination with radiation therapy in patients with metastatic sarcoma. G100 is an investigational immuno-oncology agent designed to generate a robust anti-tumor immune response when administered directly to the tumor micro-environment. The investigator-sponsored trial is being conducted at the Fred Hutchinson Cancer Research Center.

"We look forward to investigating the potential of G100 in combination with radiation therapy to induce an immune response in patients with metastatic soft tissue sarcoma, an aggressive disease with limited treatment options," said Seth Pollack, M.D., Fred Hutchinson Cancer Research Center and principal investigator. "G100 is designed to activate antigen presenting cells (APCs) and boost pre-existing anti-tumor cytotoxic T cells or CTLS. In addition, radiation therapy can lead to lysis of tumor cells that release tumor antigens that can be recognized by APCs. The combination of intra-tumoral G100 with local radiation is expected to boost the immune system's response to tumor antigens in the tumor microenvironment and lead to a broad, systemic anti-tumor response."

The Phase 1 open label trial is designed to evaluate the safety, clinical efficacy and immunogenicity of intra-tumoral G100 in combination with palliative radiation therapy in patients with metastatic soft tissue sarcoma. Per protocol, patients will receive treatment with G100 weekly starting prior to the radiation therapy and continuing for eight weeks, and efficacy will be evaluated based on radiographic response in metastatic lesions.

"We are pleased that intra-tumoral administration of G100 is now being actively studied in two indications - metastatic soft tissue sarcoma and Merkel cell carcinoma - both alone and in combination with local radiation," said Richard Kenney, M.D., Chief Medical Officer of Immune Design. "The key component of G100, GLA, has been evaluated in more than 1,000 subjects and has demonstrated the ability to stimulate both the innate and adaptive immune system while being well tolerated."

About G100 and the Endogenous Antigen Approach

G100 is an investigational agent that is a product of the company's GLAAS™ 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 "Endogenous Antigen" approach to treating cancer, which leverages the activation of dendritic cells in the tumor microenvironment, potentially to 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 is also currently underway and a Phase 1 study of G100 in combination with local radiation in patients with non-Hodgkin lymphoma is planned for the second quarter of this year.

Clinical Development Beyond G100

In addition to the Endogenous Antigen approach, Immune Design has a separate immuno-oncology approach known as "Specific Antigen" that utilizes its ZVex™ platform to deliver specific tumor antigen genes directly to cancer patients' dendritic cells *in vivo*. The company is pursuing this approach simultaneously through its LV305 and CMB305 clinical programs. The Specific and Endogenous Antigen programs constitute independent approaches that offer the potential to benefit patients with a wide range of both accessible and inaccessible tumors, as well as the opportunity to be combined with other immuno-oncology approaches such as checkpoint inhibitors and *ex vivo* engineered T cells.

For Patients

More information about this study, including additional eligibility criteria and contact information, can be found on clinicaltrials.gov.

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 enhancing other immune effectors, to fight cancer and other chronic diseases. Immune Design's three on-going immuno-oncology clinical programs are the product 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 Regarding 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," "believe" 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 statements regarding expectations about the ability of G100 with local radiation to boost the immune system and to generate an anti-tumor response and the timing and likelihood of commencing a third clinical trial evaluating G100 in combination with local radiation in non-Hodgkin lymphoma. Factors that may cause 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 (the "SEC"), including the "Risk Factors" section of Immune Design's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2014 and in any subsequent filings with the SEC. 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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