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Immune Design and Merck to Collaborate on Combination Trials of Two Immune Design Immunotherapies With Merck's KEYTRUDA for Non-Hodgkin's Lymphoma and Melanoma

Phase 1 Trials to Evaluate Investigational Agents G100 or LV305 Combined With Merck's KEYTRUDA(R) (pembrolizumab)

SEATTLE, SOUTH SAN FRANCISCO, Calif. and KENILWORTH, N.J., Aug. 10, 2015 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ) today announced it has entered into clinical collaboration agreements through subsidiaries of Merck (NYSE:MRK), known as MSD outside of the United States and Canada, to evaluate the safety and efficacy of two Immune Design immuno-oncology investigative agents, G100 and LV305, separately combined with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in Phase 1 trials in patients with non-Hodgkin's lymphoma (NHL) and melanoma, respectively.

The first clinical trial will examine intratumoral administration of G100 with intravenous administration of KEYTRUDA in patients with follicular NHL receiving local radiation. In addition to an evaluation of the safety of the combination, the study will assess the response in both injected and non-injected lesions. The second clinical trial in melanoma will evaluate safety and response to the combination of LV305 and KEYTRUDA in patients who have not yet responded to treatment with KEYTRUDA alone after three months of treatment.

Immune Design's G100 and LV305 investigational agents are designed to work *in vivo* and activate the immune system via the induction and/or expansion of anti-tumor CD8 T cells. They are intended to be "off-the-shelf" therapies, in contrast to other T-cell approaches that require individualized *ex vivo* manipulation. G100 is a potent toll-like receptor-4 (TLR4) agonist designed to generate a robust anti-tumor immune response when administered directly to the tumor micro-environment. LV305, in contrast, is designed to activate the immune system through the *in vivo* generation of cytotoxic T cells (CTLs), initially against a specific tumor-associated antigen, NY-ESO-1. Immune Design is studying LV305 primarily as part of CMB305, a prime boost approach currently in a Phase 1 expansion trial.

"There is great potential to expand the potential of immunotherapy through combination approaches that will stimulate and enhance the immune system in order to mount the strongest response against cancer," said Carlos Paya, M.D., Ph.D, President and Chief Executive Officer of Immune Design. "Immune Design has two distinct approaches in oncology, and we look forward to collaborating with Merck to evaluate the potential of combining each of G100 and LV305 with KEYTRUDA in these areas of medical need."

"Our understanding of the immune system's role and its impact in the treatment of cancer continues to grow," said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. "This collaboration with Immune Design adds to a broad clinical program designed to explore the role of KEYTRUDA in innovative immuno-oncology combinations - and underscores our commitment to advance the care of patients with cancer."

About G100

G100 is a product candidate generated from 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 intratumoral immune activation, or 'Endogenous Antigen' approach to treating cancer, which leverages the activation of dendritic cells, T cells and other immune cells in the tumor microenvironment to potentially 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. In addition to the study planned under this collaboration, a Phase 1 study of G100 in patients with Merkel cell carcinoma (MCC) recently completed enrollment, and Immune Design presented data at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting, the poster for which can be accessed on the company's website. In the first eight patients in MCC study, G100 has an acceptable safety profile and a fifty percent (50%) objective response rate per protocol.

About LV305

LV305, generated from Immune Design's ZVex™ platform, is designed to activate the immune system through the *in vivo* generation of cytotoxic T cells (CTLs) initially against a specific tumor-associated antigen, NY-ESO-1. LV305 is part of Immune Design's 'Specific Antigen' approach, which drives the *in vivo* generation of a strong, antigen-specific CTL response against selected antigens present in a tumor. Preclinical tests have demonstrated the ability of LV305 to reduce tumor growth of NY-ESO-1-expressing tumors, increase production of antigen-specific CD8 cells, and significantly improve the survival of tumor-

bearing animals. LV305 is the first step in Immune Design's novel prime-boost approach to immuno-oncology, which includes combination with G305, generated from the GLAAS platform, to expand CTLs and potentially generate a potent, durable immune response. Immune Design announced positive data from a Phase 1 study of LV305 at the 2015 ASCO Annual Meeting, the poster for which can be accessed on the company's website. In that study, LV305 caused either a *de novo* or statistically-significant increase in antigen-specific CD8 T cells in 80% of the six evaluable mid- and high-dose patients. Immune Design is primarily studying LV305 as part of CMB305, a prime boost approach.

About KEYTRUDA® (pembrolizumab)

KEYTRUDA (pembrolizumab) is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2. By binding to the PD-1 receptor and blocking the interaction with the receptor ligands, KEYTRUDA releases the PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response.

KEYTRUDA is indicated in the United States at a dose of 2 mg/kg administered as an intravenous infusion over 30 minutes every three weeks for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication is approved under accelerated approval based on tumor response rate and durability of response. An improvement in survival or disease-related symptoms has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Merck is advancing a broad and fast-growing clinical development program for KEYTRUDA with more than 100 clinical trials - across more than 30 tumor types and over 16,000 patients - both as a monotherapy and in combination with other therapies.

Selected Important Safety Information for KEYTRUDA

Pneumonitis occurred in 12 (2.9%) of 411 patients with advanced melanoma receiving KEYTRUDA (the approved indication in the United States), including Grade 2 or 3 cases in 8 (1.9%) and 1 (0.2%) patients, respectively. Monitor patients for signs and symptoms of pneumonitis. Evaluate suspected pneumonitis with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold KEYTRUDA for Grade 2; permanently discontinue KEYTRUDA for Grade 3 or 4 pneumonitis.

Colitis (including microscopic colitis) occurred in 4 (1%) of 411 patients, including Grade 2 or 3 cases in 1 (0.2%) and 2 (0.5%) patients respectively, receiving KEYTRUDA. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold KEYTRUDA for Grade 2 or 3; permanently discontinue KEYTRUDA for Grade 4 colitis.

Hepatitis (including autoimmune hepatitis) occurred in 2 (0.5%) of 411 patients, including a Grade 4 case in 1 (0.2%) patient, receiving KEYTRUDA. Monitor patients for changes in liver function. Administer corticosteroids for Grade 2 or greater hepatitis and, based on severity of liver enzyme elevations, withhold or discontinue KEYTRUDA.

Hypophysitis occurred in 2 (0.5%) of 411 patients, including a Grade 2 case in 1 and a Grade 4 case in 1 (0.2% each) patient, receiving KEYTRUDA. Monitor for signs and symptoms of hypophysitis (including hypopituitarism and renal insufficiency). Administer corticosteroids for Grade 2 or greater hypophysitis. Withhold KEYTRUDA for Grade 2; withhold or discontinue for Grade 3; and permanently discontinue KEYTRUDA for Grade 4 hypophysitis.

Hyperthyroidism occurred in 5 (1.2%) of 411 patients, including Grade 2 or 3 cases in 2 (0.5%) and 1 (0.2%) patients, respectively, receiving KEYTRUDA. Hypothyroidism occurred in 34 (8.3%) of 411 patients, including a Grade 3 case in 1 (0.2%) patient, receiving KEYTRUDA. Thyroid disorders can occur at any time during treatment. Monitor patients for changes in thyroid function (at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation) and for clinical signs and symptoms of thyroid disorders. Administer corticosteroids for Grade 3 or greater hyperthyroidism. Withhold KEYTRUDA for Grade 3; permanently discontinue KEYTRUDA for Grade 4 hyperthyroidism. Isolated hypothyroidism may be managed with replacement therapy without treatment interruption and without corticosteroids.

Type 1 diabetes mellitus, including diabetic ketoacidosis, has occurred in patients receiving KEYTRUDA. Monitor patients for hyperglycemia and other signs and symptoms of diabetes. Administer insulin for type 1 diabetes, and withhold KEYTRUDA in cases of severe hyperglycemia until metabolic control is achieved.

Nephritis occurred in 3 (0.7%) patients receiving KEYTRUDA, consisting of one case of Grade 2 autoimmune nephritis (0.2%) and two cases of interstitial nephritis with renal failure (0.5%), one Grade 3 and one Grade 4. Monitor patients for changes in renal function. Administer corticosteroids for Grade 2 or greater nephritis. Withhold KEYTRUDA for Grade 2; permanently discontinue KEYTRUDA for Grade 3 or 4 nephritis.

Other clinically important immune-mediated adverse reactions can occur. The following clinically significant, immune-mediated adverse reactions occurred in patients treated with KEYTRUDA: exfoliative dermatitis, uveitis, arthritis, myositis, pancreatitis, hemolytic anemia, partial seizures arising in a patient with inflammatory foci in brain parenchyma, severe dermatitis including

bullous pemphigoid, myasthenic syndrome, optic neuritis, and rhabdomyolysis.

For suspected immune-mediated adverse reactions, ensure adequate evaluation to confirm etiology or exclude other causes. Based on the severity of the adverse reaction, withhold KEYTRUDA and administer corticosteroids. Upon improvement of the adverse reaction to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Restart KEYTRUDA if the adverse reaction remains at Grade 1 or less. Permanently discontinue KEYTRUDA for any severe or Grade 3 immune-mediated adverse reaction that recurs and for any life-threatening immune-mediated adverse reaction.

Infusion-related reactions, including severe and life-threatening reactions, have occurred in patients receiving KEYTRUDA. Monitor patients for signs and symptoms of infusion-related reactions including rigors, chills, wheezing, pruritis, flushing, rash, hypotension, hypoxemia, and fever. For severe or life-threatening reactions, stop infusion and permanently discontinue KEYTRUDA.

Based on its mechanism of action, KEYTRUDA may cause fetal harm when administered to a pregnant woman. If used during pregnancy, or if the patient becomes pregnant during treatment, apprise the patient of the potential hazard to a fetus. Advise females of reproductive potential to use highly effective contraception during treatment and for 4 months after the last dose of KEYTRUDA.

For the treatment of advanced melanoma, KEYTRUDA was discontinued for adverse reactions in 9% of 411 patients across all doses studied. Serious adverse reactions occurred in 36% of patients receiving KEYTRUDA. The most frequent serious adverse drug reactions reported in 2% or more of patients were renal failure, dyspnea, pneumonia, and cellulitis.

The most common adverse reactions (reported in at least 20% of patients) were fatigue (47%), cough (30%), nausea (30%), pruritus (30%), rash (29%), decreased appetite (26%), constipation (21%), arthralgia (20%), and diarrhea (20%).

The recommended dose of KEYTRUDA is 2 mg/kg administered as an intravenous infusion over 30 minutes every three weeks until disease progression or unacceptable toxicity. No formal pharmacokinetic drug interaction studies have been conducted with KEYTRUDA. It is not known whether KEYTRUDA is excreted in human milk. Because many drugs are excreted in human milk, instruct women to discontinue nursing during treatment with KEYTRUDA. Safety and effectiveness of KEYTRUDA have not been established in pediatric patients.

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.

Forward-Looking Statement of Immune Design

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.

Merck's Focus on Cancer

Our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer worldwide. At

Merck Oncology, helping people fight cancer is our passion and supporting accessibility to our cancer medicines is our commitment. Our focus is on pursuing research in immuno-oncology and we are accelerating every step in the journey - from lab to clinic - to potentially bring new hope to people with cancer. For more information about our oncology clinical trials, visit www.merck.com/clinicaltrials.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside of the United States and Canada. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2014 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

Please see Prescribing Information for KEYTRUDA (pembrolizumab) at http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf and the Medication Guide for KEYTRUDA at http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_mg.pdf

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