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Immune Design Announces Advancement of First GLAAS™-based Allergy Program into Clinical Development

Partner Sanofi commences dosing in peanut allergy Phase 1 trial leveraging GLAAS

SEATTLE and SOUTH SAN FRANCISCO, Calif., Sept. 28, 2016 (GLOBE NEWSWIRE) -- Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company focused on cancer, today announced the application of its GLAAS discovery platform in Sanofi's Phase 1 clinical trial evaluating a novel therapeutic candidate for the treatment of peanut allergy. The trial follows an exclusive license agreement with Immune Design to discover, develop and commercialize products to treat a peanut allergy utilizing the company's GLAAS™ discovery platform.

Sanofi's Phase 1 trial is designed to evaluate the safety of the product candidate in healthy volunteers. Under a previous collaborative research arrangement, Sanofi and IMDZ generated significant preclinical data demonstrating that certain formulations of GLA, the core of the GLAAS platform, when given prophylactically or therapeutically, can shift the immune responses in a way that may result in significant protection and reduction from allergy symptoms. Immune Design has received an undisclosed milestone payment for start of the trial, and is eligible to receive future development and commercialization milestones, as well as tiered royalties on sales of approved products.

"This is the first expansion of the GLAAS platform into allergic diseases, adding to the existing clinical programs in cancer and infectious diseases," said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design. "The GLAAS mechanism of action is designed to help correct imbalances related to immune dysfunction that leads to allergic diseases. The progress of this program into clinical development and GLAAS' robust preclinical data package supports the potential to leverage GLAAS in additional programs in other allergic disease indications."

About Food and Peanut Allergy

The incidence of food allergies is increasing worldwide in both developed and undeveloped countries, and especially in children.[1] Globally, experts believe 220-250 million people may suffer from food allergies.[1] In the United States alone, as many as 15 million people have food allergies,[2] with allergic reactions resulting in an emergency room visit every three minutes and averaging more than 200,000 emergency room visits per year.[3] Peanut allergen is the most prevalent, representing approximately 25% amongst food-allergic children in the U.S.[4]

About GLAAS

Immune Design's GLAAS platform works *in vivo* and is based on a small synthetic molecule called GLA, or glucopyranosyl lipid A. GLA selectively binds to the TLR4 receptor and causes potent activation of dendritic cells (DCs) leading to the production of cytokines and chemokines that drive a Th1-type immune response. When GLA is accompanied by an antigen and injected into a patient, the combination is taken up by DCs and leads to the production and expansion of immune cells called CD4 T helper lymphocytes with a Th1 phenotype. These CD4 T cells play a key role in boosting pre-existing CTLs that are specific to the same antigen, neutralize a Th2 phenotype, and provide help to other immune cells and natural killer cells that are also important in the overall immune response. GLA can also be used to induce local and systemic immune responses against cancer by directly injecting it into tumors, where it induces a pro-inflammatory state of the tumor microenvironment. Immune Design believes that GLAAS product candidates have the potential to target multiple types of cancer, as well as infectious, allergic and autoimmune diseases. GLAAS-based product candidates have now been evaluated in over 1400 subjects in Phase 1 and Phase 2 trials demonstrating an acceptable safety profile.

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 two-pronged focus of Immune Design's ongoing 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 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, timing and results of clinical trials and the potential receipt of future milestone payments and royalties on sales of approved products. 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 enrolment 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.

References

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