

August 7, 2014

Sanofi Licenses Immune Design's GLAAS Platform to Explore Novel Approach to Treat Food Allergy

CAMBRIDGE, Mass. and SEATTLE and SOUTH SAN FRANCISCO, Calif., Aug. 7, 2014 (GLOBE NEWSWIRE) -- Sanofi (EURONEXT:SAN) (NYSE:SNY) and Immune Design (Nasdaq:IMDZ), a clinical-stage immunotherapy company, today announced that they have entered into a licensing agreement for use of Immune Design's GLAAS™ discovery platform to develop therapeutic agents to treat a selected food 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.^{2,3} In the United States alone, as many as 15 million people have food allergies,⁴ with allergic reactions resulting in an emergency room visit every three minutes and averaging more than 200,000 emergency room visits per year.⁵

"This is an exciting time in the area of immunology research, and our relationship with Immune Design is a great example of how Sanofi has changed our approach to R&D," said Kurt Stoeckli, vice president and head of Global Bio Therapeutics Organization, Sanofi. "With this partnership, we are able to tap into breakthrough science that holds great potential to transform how food allergies are treated, and the lives of those people affected. This kind of innovation is central to our new approach."

Under terms of the agreement, Immune Design has granted Sanofi an exclusive license to discover, develop and commercialize products to treat a selected food allergy. The company has received an undisclosed upfront payment and will be eligible to receive development and commercialization milestones totaling US \$168 million, as well as tiered royalties on sales of approved products.

"Our fourth agreement for the use of the GLAAS platform further demonstrates the broad applicability of this approach not only in cancer and infectious diseases, but now in allergic diseases as well," said Stephen Brady, chief business officer at Immune Design. "Due to the immune dysfunction leading to allergic diseases, GLAAS' mechanism of action is well suited to correct the imbalance, allowing for the potential of new therapeutics in the targeted indication that currently uses century-old technologies. We are pleased that Sanofi has decided to develop products for this often life-threatening and growing food allergy."

Under an existing collaborative research arrangement, Sanofi and Immune Design have generated a large set of preclinical data demonstrating that certain formulations within GLAAS, when given prophylactically or therapeutically, can shift the immune responses in a way that may result in significant protection and reduction from allergy symptoms.

About Sanofi

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, and consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT:SAN) and in New York (NYSE:SNY).

About GLAAS

Immune Design's GLAAS platform works *in vivo* and is based on a small synthetic molecule called GLA, which stands for glucopyranosyl lipid adjuvant. 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; and providing help to other immune cells, including B lymphocytes that are the precursor to antibodies, and natural killer cells that are also important in the overall immune response. 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 1000 subjects in Phase 1 and Phase 2 trials demonstrating an acceptable safety profile and efficacy.

About Immune Design

Immune Design (Nasdaq:IMDZ) 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 create tumor-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: DCVex™ and GLAAS™, the fundamental technologies of which were licensed from the California Institute of Technology and the Infectious Disease Research Institute, respectively. Immune Design has offices in Seattle, Washington and South San Francisco, California. For more information, visit www.immunedesign.com.

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2013. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Immune Design 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 the receipt of milestone and royalty payments, the potential to develop new therapeutics and the potential of any future products to prevent and reduce allergy symptoms. 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, including the "Risk Factors" 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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