



## Sanofi Pasteur and Immune Design Collaborate on a Vaccine to Treat Herpes Simplex Virus

*- The two companies will develop a product jointly through phase II -*

**Lyon, France - October 16, 2014** - [Sanofi Pasteur](#), the vaccines division of [Sanofi](#) and [Immune Design Corp.](#), a clinical-stage immunotherapy company, today announced that they have entered into a broad collaboration for the development of a herpes simplex virus (HSV) immune therapy.

Sanofi Pasteur and Immune Design will each contribute product candidates to the collaboration: Sanofi Pasteur will contribute HSV-529, a clinical-stage replication-defective HSV vaccine product candidate, and Immune Design will contribute G103, its preclinical trivalent vaccine product candidate. The collaboration will explore the potential of various combinations of agents, including Immune Design's GLAAS™ platform, with the goal to select the best potential immune therapy for patients.

*"We intend to develop the best in class HSV therapeutic vaccine by pooling assets of Sanofi Pasteur and of Immune Design,"* explained John Shiver, PhD, Senior VP for R&D, Sanofi Pasteur. *"Given the challenges of vaccine development,"* Shiver continued, *"collaborations are important to help ensure that the medical need will eventually be met."*

The two companies will develop the products jointly through Phase II clinical trials, at which point Sanofi Pasteur intends to continue development of the most promising candidate and be responsible for commercialization. Sanofi Pasteur will bear the costs of all preclinical and clinical development, with Immune Design providing a specific formulation of GLA from the GLAAS platform at its cost through Phase II studies. Immune Design will be eligible to receive future milestone and royalty payments on any product developed from the collaboration; other financial terms of the agreement have not been disclosed.

### 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 cytotoxic T cells 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.

### About Sanofi Pasteur's HSV Vaccine Program

Sanofi Pasteur's HSV vaccine candidate is classified as a replication-defective virus, where the virus possesses all the components of wild-type virus with the exception of two proteins that are involved in viral DNA replication. The vaccine candidate is still capable of infecting cells but does



not have the necessary machinery to undergo replication and establish latent or long-term infection. Because of these attributes, the candidate is capable of eliciting a broad immune response, both a B-cell and T-cell response that is directed against the majority of the antigenic components of the virus. The investigative vaccine is currently being studied in a phase I trial sponsored by the U.S. National Institutes of Health (NIH) in people with the infection as well as those without in the United States. Due to the lengthy follow-up of volunteers in the trial, results are expected in 2016. Encouraging preclinical results have been generated by the vaccine candidate where protection against infection has been demonstrated in the guinea pig genital herpes challenge model.

### **About HSV**

Herpes is a common sexually transmitted disease (STD) that any sexually active person can acquire. Most people with the virus don't have symptoms. It is important to know that even without signs of disease, it can still spread to sexual partners. You can get herpes by having vaginal, anal, or oral sex with someone who has the disease. Fluids found in a herpes sore carry the virus, and contact with those fluids can cause infection. You can also get herpes from an infected sex partner who does not have a visible sore or who may not know that he or she is infected, because the virus can be released through your skin and spread the infection to your sex partner(s). Genital herpes is common in the United States, as about one out of every six people aged 14 to 49 years have genital herpes.<sup>1</sup>

### **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, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: [SAN](#)) and in New York (NYSE: [SNY](#)).

Sanofi Pasteur, the vaccines division of Sanofi, provides more than 1 billion doses of vaccine each year, making it possible to immunize more than 500 million people across the globe. A world leader in the vaccine industry, Sanofi Pasteur offers a broad range of vaccines protecting against 20 infectious diseases. The company's heritage, to create vaccines that protect life, dates back more than a century. Sanofi Pasteur is the largest company entirely dedicated to vaccines. Every day, the company invests more than EUR 1 million in research and development. For more information, please visit: [www.sanofipasteur.com](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://www.sanofipasteur.us)

<sup>1</sup> <http://www.cdc.gov/std/herpes/STDFact-herpes.htm> Accessed September 22, 2014

### **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.*

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