



BARDA Grants \$43.2 million USD to Sanofi Pasteur for Zika

- Funds will be used for phase II development and manufacturing -

Paris, France - September 26, 2016 - [Sanofi](#) and its vaccines global business unit [Sanofi Pasteur](#) announced today that the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services has agreed to a proposal to fund the manufacture of an inactivated Zika vaccine for phase II development. Sanofi Pasteur committed to researching and developing a vaccine to prevent Zika in February, shortly after the World Health Organization declared an emergency.

In July 2016, Sanofi Pasteur announced a Cooperative Research and Development Agreement with the Walter Reed Army Institute of Research (WRAIR) on the co-development of a Zika vaccine candidate. The BARDA funding is to take WRAIR's Zika purified inactivated virus (ZPIV) vaccine into phase II development with manufacturing and characterization of the vaccine product as well as optimization of the upstream process to improve production yields.

Sanofi Pasteur is in the process of creating a clinical development and regulatory strategy while WRAIR and the National Institute of Allergy and Infectious Diseases (NIAID)—part of the U.S. National Institutes of Health (NIH)—are conducting a series of phase I ZPIV trials. Beyond the funding provided by BARDA for the two phase I/II clinical trials, there is an option in the contract that BARDA can exercise for continuing support through Phase III industrial and clinical development.

“Given the devastating effects that this infectious disease can have on babies of infected mothers and the fact that the disease appears to rapidly spread, Sanofi Pasteur decided to get involved early on” said David Loew, Sanofi Executive Vice President and Head of Sanofi Pasteur. “We are very pleased that the U.S. government is committed to working with us to develop a Zika vaccine. Based on this collaboration, we can bring together resources and expertise which are essential in fighting this public-health concern.”

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public-health medical emergencies. The project has been funded with Federal funds from BARDA under Contract HHSO100201-6000039C.

Sanofi Pasteur has developed and provides several vaccines against flaviviruses, such as yellow fever, dengue, and Japanese encephalitis. It developed its first yellow fever vaccine in 1979 and



has since sold more than 400 million doses; it is licensed in more than 100 countries around the world. In 2010 Sanofi Pasteur licensed its first vaccine against Japanese encephalitis, which is now licensed in 14 countries with more than 1.5 million doses sold to date. Both yellow fever and Japanese encephalitis vaccines are licensed in endemic countries as well as other countries for travelers. Sanofi Pasteur's newest flavivirus vaccine is licensed for the prevention of dengue fever in several endemic countries; Dengvaxia[®] was first licensed in Mexico, the Philippines and Brazil late last year and picked up six more licensures so far this year in El Salvador, Costa Rica, Paraguay, Guatemala, Peru and Indonesia.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and 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 produces a portfolio of high quality vaccines that matches its areas of expertise and meets public-health demand. 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 or www.sanofipasteur.us

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, Sanofi's ability to benefit from external growth opportunities and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives 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, 2015. 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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