



Sanofi Pasteur, Fiocruz, and WRAIR Agree to Collaborate on Zika Vaccine Research

- The three research organizations have a history of flavivirus vaccine collaboration -

Paris, France - October 27, 2016 - [Sanofi](#) and its vaccines global business unit [Sanofi Pasteur](#), announced today that it has agreed to Principles of Collaboration with the Oswaldo Cruz Foundation-- by means of its Immuno-biological Technology Institute known as Bio-Manguinhos/Fiocruz—and the Walter Reed Army Institute of Research (WRAIR)--a United States Department of Defense Laboratory—regarding Zika vaccine development. This collaboration follows the signing this past summer of a Cooperative Research and Development Agreement (CRADA) between WRAIR and Sanofi Pasteur to conduct research and development of a Zika vaccine using WRAIR's inactivated-virus vaccine (ZPIV) technology.

Under the Principles of Collaboration, Fiocruz, WRAIR and Sanofi Pasteur intend to combine their expertise in the fight against Zika. Fiocruz's activities will complement WRAIR and Sanofi Pasteur's activities, provide additional expertise, and increase the likelihood of successfully developing and licensing a safe and effective Zika vaccine as quickly as possible.

According to the CRADA signed by WRAIR and Sanofi Pasteur, WRAIR is providing its Zika purified, inactivated-virus vaccine (ZPIV) candidate to Sanofi Pasteur to produce clinical material in compliance with current GMP (Good Manufacturing Practices) to support phase II testing, optimize the upstream process to improve production yields, and characterize the vaccine product. WRAIR—along with the U.S. National Institute for Allergy and Infectious Diseases (NIAID)--will sponsor and support a series of phase 1 trials.

Last month 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 agreed to a proposal to fund Sanofi's manufacture of the inactivated Zika vaccine for phase II development. Sanofi Pasteur is in the process of creating a clinical development and regulatory strategy while WRAIR and NIAID are conducting the 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

Building on the WRAIR partnership, areas of collaboration with Fiocruz could include process development, vaccine characterization, epidemiological studies, pre-clinical and clinical evaluation of a vaccine, as well as clinical assay optimization.

"Fiocruz, WRAIR, and Sanofi Pasteur have a history of collaborating," explained John Shiver, PhD, Sr. VP for R&D at Sanofi Pasteur. "It only makes sense for the pursuit of public health that we combine our expertise and resources on Zika with Fiocruz, which is ideally based in Brazil where the heart of the current Zika experience lies. We have a common goal of developing a vaccine to prevent this emerging disease threat imposed by the Zika virus."



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, Dengvaxia[®], is licensed for the prevention of dengue fever in 12 endemic countries to date, including Brazil.

About The Oswaldo Cruz Foundation

The Oswaldo Cruz Foundation (Portuguese Fundação Oswaldo Cruz, also known as FIOCRUZ) is a scientific institution founded in 1900 for research and development in biomedical sciences located in Rio de Janeiro and 10 other Brazilian states. FIOCRUZ has a broad mandate related to the health and wellbeing of the Brazilian population. Its Bio-Manguinhos institute is one of the world's top public-health research institutions involved in vaccines--such as meningococcal ACW, yellow fever, poliomyelitis, human rotavirus, measles, mumps and rubella (MMR)—as well as drug development diagnostic kits, the training of public health and other healthcare workers, and providing information and communications related to health, science, and technology. Recently, Fiocruz has been collaborating with the World Health Organization (WHO) to solve the yellow fever epidemic in Africa.

About The Walter Reed Army Institute of Research

Headquartered in Silver Spring, Maryland, the Walter Reed Army Institute of Research (WRAIR) develops vaccines, drugs and diagnostics for current and emerging diseases that pose a threat to military operations and readiness. With a wide presence in Africa and Asia, and a new unit in the Caucasus region, WRAIR conducts research where infectious disease threats are greatest.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Merial. 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

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, 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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