



## **Shantha Biotechnics' Inactivated Polio Vaccine – ShanIPV™ prequalified by the World Health Organization (WHO)**

- First to partner with the Indian Government for IPV since India was declared polio-free -
- Provided 28+ mn doses of ShanIPV™ to the Indian Government since 2015 -

**National, 24th October 2018:** Sanofi Pasteur, the vaccines division of Sanofi, is proud to announce today that its standalone IPV (Inactivated Polio Vaccine) – ShanIPV™, developed by its affiliate Shantha Biotechnics, has received prequalification status from the World Health Organization (WHO). This status qualifies ShanIPV™ vaccine for purchase by the United Nations' agencies.

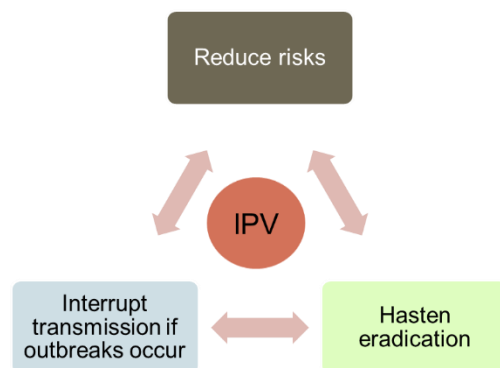
The WHO prequalification programme is a service provided to the United Nations' procurement agencies. The goal of the programme is to ensure that the vaccines used in immunization programmes are safe and effective, the vaccine efficacy data and studies are relevant to the target population, and that the vaccine meets the specific needs of the programme, reflected by the tender specifications: i.e. potency, thermostability, presentation, labeling, shipping conditions, etc.

*“WHO-prequalification of a vaccine is a stringent process wherein the WHO reviews the production process, quality control procedures, tests consistency of various batches and works closely with the responsible National Regulatory Authority in this process. The prequalification is testament to our commitment to provide high quality vaccines. ShanIPV™ plays a crucial part in keeping India polio-free and we are proud to have supplied more than 28 million doses of this vaccine to the Indian Government since 2015.”* **said Dr. Mahesh Bhalgat, Executive Director & COO, Shantha Biotechnics, a Sanofi Pasteur company.**

*“Over the last two decades, Sanofi Pasteur has been serving the vaccination needs of India by making available the highest quality products. Today, the only 2 WHO-prequalified IPV containing vaccines that are available in India are both from Sanofi Pasteur (ShanIPV™ and Hexaxim®). Through our partnership with the Government of India, I'm proud to share that every one-out-of-two babies born in the country is protected with an IPV from Sanofi Pasteur.”* **said Jean-Pierre Baylet, Country Head – Sanofi Pasteur, India & South Asia.**



India is currently in its fifth year of being polio-free and its seventh, since the last reported polio case. According to the GPEI (Global Polio Eradication Initiative) Endgame Strategic Plan 2013-2018, introducing at least one dose of IPV in current polio eradication programs and completely switching from OPV to IPV in the next few years, is critical to ending polio transmission. As per the dashboard of India's Ministry of Health & Family Welfare (April 2018), the coverage of IPV dose 1 is 62% and that of dose 2 is 52%.



Given India's high birth cohort, Sanofi Pasteur has invested significantly over the years to ensure access to high-quality vaccination against polio for a large number of babies in India.

### About Shantha Biotechnics

Shantha Biotechnics, which was acquired by Sanofi Pasteur Holding in 2009, is a biotechnology pioneer from the emerging countries, founded by Dr. K I Varaprasad Reddy in 1993 in Hyderabad, India. Shantha is a fully integrated biotechnology company involved in R&D, manufacturing and marketing.

Shantha's mission is to develop, produce and market human healthcare products that are affordable and meet the highest International standards. Shantha's products complement Sanofi Pasteur's vaccine portfolio. Five of its licensed vaccines are WHO-prequalified: Shan5™ pediatric vaccine, Shanchol™ cholera vaccine, Shanvac-B® hepatitis B vaccine, ShanTT™ tetanus vaccine and ShanIPV™ polio vaccine.

### About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life



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. Sanofi Pasteur invests more than EUR 500 million in research and development every year. For more information, please visit: [www.sanofipasteur.com](http://www.sanofipasteur.com) or [www.sanofipasteur.us](http://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, 2016. 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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