



Shantha Biotechnics's cholera vaccine completes milestone of delivering 10 million doses

This impacts public health through potential benefit to ~5 million lives across 25 countries

Hyderabad, 5 July 2017: Shantha Biotechnics, the Hyderabad based affiliate of Sanofi Pasteur (the vaccines division of Sanofi), announced today its milestone achievement of having delivered 10 million doses of its cholera vaccine, Shanchol™. The vaccine received the World Health Organization (WHO) pre-qualification in 2011 and since then, the product has been shipped to 25 countries across the world. The WHO Prequalification of Medicines Programme ensures that medicines meet acceptable standards of quality, safety and efficacy.

In 2011, the World Health Assembly recognized the re-emergence of cholera as a significant public health burden and threat. Major cholera outbreaks around the world have been reported from the Democratic Republic of the Congo, Haiti, the Horn of Africa, Mozambique, South Sudan and Yemen.

*“We estimate that the 10 million doses of Shanchol™ could potentially have saved close to five million people – especially those living in high-risk, endemic areas - from cholera. Since 2013, Shantha Biotechnics's impact on public health through the supply of oral cholera vaccine to WHO has contributed significantly to global cholera control.” said **Dr. Shailesh Ayyangar**, Managing Director - India and Vice President - South Asia, Sanofi.*

Cholera, an acute watery diarrheal disease, caused by toxigenic strains of the bacterium *Vibrio cholerae* O1 and O139, is estimated to cause more than 2.9 million cases and 95,000 deaths annually in cholera endemic countries alone, and frequent epidemics in other settings that have poor water and sanitation infrastructure. According to a paper published by SAGE Working Group on Oral Cholera Vaccines, the WHO Secretariat, and the Centers for Disease Control and Prevention in March 2017, globally the disease estimates range from 1.4 – 4.8 million cases and 28,000 – 142,000 deaths every year.

*“There were many occasions when the time to deliver the vaccines was very short. In October 2016, the WHO asked Shantha Biotechnics to deliver 510,000 doses of Shanchol™ to Iraq. The Ministry of Health in Iraq wanted to launch a major vaccination campaign to combat a cholera outbreak situation. This was the single biggest shipment of cholera vaccine which Shantha delivered within eleven days.” said **Dr. Mahesh Bhalgat**, Executive Director and Chief Operating Officer, Shantha Biotechnics.*

Shanchol™ is a ready to use oral cholera vaccine adapted to endemic settings. It consists of killed whole cells from a mix of pathogenic strains of the cholera bacterium *Vibrio cholerae* (O1 and O139) and is administered in two doses, one to six weeks apart. It is a fast-acting vaccine (7 to 10 days) and provides long-lasting protection for up to 5 years from the time of administration.

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. Four of its licensed vaccines are WHO-prequalified: Shan5™ pediatric vaccine, Shanchol™ cholera vaccine, Shanvac-B® hepatitis B vaccine, and ShanTT™ tetanus vaccine. Sanofi Pasteur and Shantha are also developing a new pediatric combination vaccine based on Shan5™ that will incorporate Sanofi Pasteur's Inactivated Polio Vaccine (IPV) in order to secure polio eradication.

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 Consumer Healthcare. 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

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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