WHO approves Cholera vaccine from Shantha Biotechnics for use at temperatures as high as 40°C for up to 14 days, immediately prior to administration

- ***First Cholera vaccine in the world to receive a stamp of approval for storage and distribution outside the traditional cold chain***
- ***Improves patient access, especially in remote areas of India***

Hyderabad, India, - February 26, 2018: Sanofi Pasteur, the vaccines division of Sanofi, is proud to announce that its affiliate Shantha Biotechnics has received approval from the World Health Organisation (WHO) for Shanchol™, its oral cholera vaccine, that the vaccine may be kept for single period of time of up to 14 days at temperature of up to 40°C immediately prior to administration, provided the vaccine has not reached its expiry date and vaccine vial monitor has not reached discard point. The approval is of great significance to regions where the vaccine is used, including India, as it eliminates the challenges of maintaining the vaccine cold chain (between +2°C and +8°C to maintain vaccine potency) during transport.

Commenting on this development, Dr. Mahesh Bhalgat, Executive Director and Chief Operating Officer, Shantha Biotechnics, said, *"This is a significant milestone in our efforts towards effective cholera prevention and control. The WHO's approval will help us make Shanchol™ available to populations living in remote, hard-to-reach areas of India and other parts of the world, especially ones with erratic electricity supply."*

The WHO approval for use of Shanchol™ in controlled temperature chain (CTC) was granted after a review of its stability data. Used for prevention and control of cholera in outbreak, endemic settings during humanitarian crises, Shantha Biotechnics' Shanchol™ cholera vaccine is the second "mass campaign" vaccine and first cholera vaccine worldwide to receive such a stamp of approval for storage and distribution outside the traditional cold chain.

"Cholera is an easily preventable disease that has no place in the 21st Century," said **Anuradha Gupta, Deputy CEO of Gavi, the Vaccine Alliance.** *"This important development will make it easier to deliver vaccines to the remote areas where it is desperately needed, saving lives and contributing to the global effort to finally consign this disease to the history books."*

Responding to the WHO's approval, **N. Rajaram, Managing Director, Sanofi India**, said, *"The storage label change takes us a few steps closer to our vision of a world where no lives are lost to preventable infectious diseases, as it has the potential to significantly change cholera control efforts for the better, not only in India but also in other parts of the world where the vaccine is needed the most. It is indeed a great news as it will help increase vaccine access and decrease the cost of conducting vaccination campaigns worldwide."*

Since WHO pre-qualification in 2011, 12 million doses of Shanchol™ vaccine have been shipped to 25 countries across the world, including Democratic Republic of the Congo, Haiti, Mozambique and South Sudan. The largest ever shipment of Shanchol™ vaccine took place in September 2017 when Shantha Biotechnics responded to an urgent call for humanitarian help from international agencies and sent 900,000 doses to Nigeria to respond to a cholera epidemic in the country.

Cholera is caused by a bacterium, *vibrio cholerae*, which produces a toxin that affects the intestines. The bacterium has been at the origin of devastating epidemics worldwide throughout history. The severity of the disease is mainly correlated to the risk of severe dehydration, which can lead to death in a few hours. The disease affects the most vulnerable in urban slums, rural areas, and camps set up for refugees and internally displaced individuals, with most deaths occurring among those who don't have rapid access to health services. [1,2] According to the WHO, researchers estimate that there are 2.9 million cases and 95,000 deaths worldwide due to cholera every year.

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 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.

[1] http://www.gavi.org/support/nvs/cholera-vaccine/
[2] http://www.who.int/mediacentre/factsheets/fs107/en/.

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, 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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