



## Shantha's Investigational Rotavirus Vaccine Enters Phase III Clinical Trials in India

*- The live, oral, ready-to-use tetravalent rotavirus vaccine candidate is designed to protect young children from severe diarrhea -*

**Lyon, France - October 14, 2014** - [Sanofi Pasteur](#), the vaccines division of [Sanofi](#), announced today the start of a phase III clinical trial in India for its investigational rotavirus vaccine, developed and manufactured by its affiliate Shantha Biotechnics in Hyderabad, India. The trial is designed to show non-inferiority against a currently licensed vaccine with the use of three, ready-to-use liquid doses administered orally, starting from six-to-eight weeks of age, with the subsequent doses administered at 4 weeks intervals. Close to 1,200 volunteers are being sought at 12 clinical trial sites in India. Shantha's investigational rotavirus vaccine includes antigens against serotypes G1, G2, G3 and G4.

A phase I/II study was carried out with the long-term aim to produce a locally licensed vaccine that is safe and able to protect children against rotavirus gastroenteritis. Overall, the results showed that all three doses of the vaccine evaluated in the study were safe, well tolerated and displayed good immunogenicity (dose-response) in healthy Indian infants.<sup>1</sup>

*"We aim to provide an affordable vaccine to meet the still significant medical need in emerging markets, like India, and through partnerships with organizations like Gavi, the Vaccine Alliance", commented Olivier Charmeil, Sanofi Pasteur's President & CEO. "Sanofi Pasteur wants to be in the position to target a major role in the growing rotavirus market in developing countries, with a key focus on the Gavi market, in public markets for non-Gavi countries, as well as private segments in emerging markets."*

The World Health Organization (WHO) recommends that vaccination with rotavirus vaccines should be included in all national immunization programs.<sup>2</sup> Gavi, has established an accelerated vaccine introduction initiative with the objective of driving the sustainable introduction of rotavirus vaccine in 30 Gavi-eligible countries by 2015.<sup>3</sup> In addition, PATH, an international, non-profit organization to improve public health, is working to accelerate access to rotavirus vaccines and sustain their implementation and use in countries where children need them most urgently.<sup>4</sup>

### About Rotavirus

Rotavirus infections, caused mostly by Group A viruses, are prevalent in human populations worldwide. Although the virus can and does infect older individuals, illness caused by rotavirus can be quite severe in infants and young children. In low income countries, the median age at the primary rotavirus infection ranges from 6 to 9 months (80% occur among infants less than 1 year old) whereas in high income countries the first episode may occasionally be delayed until the age of 2-5 years, though the majority still occur in infancy (65% occur among infants less than 1 year old).<sup>1</sup>

The WHO estimates that in 2008 approximately 453,000 (420,000-494,000) rotavirus gastroenteritis (RVGE)-associated child deaths occurred worldwide. These fatalities accounted for about 5% of all child deaths and a cause-specific mortality rate of 86 deaths per 100,000 population



aged less than 5 years. About 90% of all rotavirus-associated fatalities occur in low income countries in Africa and Asia and are related to poor healthcare.<sup>1</sup>

It is estimated that one of every 260 children born each year will die from diarrhea caused by rotavirus infection by their fifth birthday.<sup>2</sup> Recent studies indicate that rotavirus causes approximately 40% of childhood diarrheal hospitalizations worldwide,<sup>3</sup> 40.7% in Sub Saharan African countries,<sup>4</sup> 33% in Nepal,<sup>5</sup> 34% in Pakistan<sup>6</sup>, 40–50% in Japan,<sup>7</sup> and around 39% in India in children less than 5 years of age.<sup>8</sup> India, with more than 1 billion people, 11% of whom are less than 5 years of age, has an especially large population at risk of clinically significant RVGE.<sup>9</sup>

There is no specific drug approved to cure or ameliorate rotavirus gastroenteritis. Since virtually all infants and young children will suffer at least one rotavirus infection and many will become infected two or more times, even in settings where good hygiene is practiced, universal immunization of infants with a vaccine is clearly the way to reduce rotavirus related morbidity, mortality, and associated medical costs.<sup>1</sup>

### **About Shantha's Rotavirus Vaccine Candidate**

Shantha's investigational vaccine is designed to prevent severe rotavirus gastroenteritis in infants and children when administered as a 3-dose series to infants between the ages of 6 to 32 weeks. Each dose is an all-in-one formulation containing an antacid. The vaccine is a live-attenuated bovine-human reassortant comprising four serotypes, G1, G2, G3 and G4, and is targeted to be safe, confer non-inferior immunogenicity to already licensed vaccines and have the ability to prevent rotavirus gastroenteritis.

### **About Shantha**

Shantha, 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 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, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new 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 offers a broad range of vaccines protecting against 20 infectious diseases. 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](http://www.sanofipasteur.com) or [www.shanthabiotech.com](http://www.shanthabiotech.com)



## References

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- <sup>2</sup> <http://www.who.int/immunization/topics/rotavirus/en/> Accessed 15 Sept 2014
- <sup>3</sup> <http://www.gavi.org/support/nvs/rotavirus/> Accessed 15 Sept 2014
- <sup>4</sup> <http://sites.path.org/rotavirusvaccine/> Accessed 15 Sept 2014
- <sup>5</sup> WHO. Rotavirus vaccines. WHO position paper - January 2013. Wkly Epidemiol Rec 2013; 88:49–64.
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## 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, the Group’s ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies 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, 2013. 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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