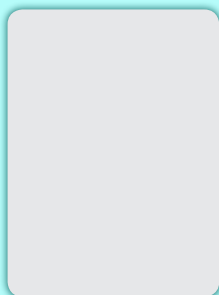


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Lopa Adhikary

Shantha Biotechnics Ltd. (Sanofi Company), India

Development path for Rota vaccine

Background: Rotavirus infection is one of the leading causes of death in children under five and accounts for half a million death per year in the world. Vaccination against Rotavirus is the best way to prevent severe Rotaviral diarrhea. Vaccines already available in the market are saving lives against severe gastroenteritis in the countries where children have access to them. The main objective of Rota vaccine program at Shantha is to develop and license a cost effective Rota vaccine in India as the Country of origin. The vaccine will subsequently be put up for UNICEF and other emerging countries.

Methods: The vaccine development follows the classical path from identification of vaccine candidate, establishing proof of concept, pre-clinical development, feasibility of scale up, clinical development, optimizing production scale; capacity based on the market demand and finally delivers quality vaccine for the customer. Each and every step of the development follows the regulatory guideline of the product. The vaccine under development is live attenuated bovine-human reassortant covering the major serotypes distribution worldwide. Vaccine strains have been grown using vero cell as substrate. Clinical batches were manufactured, validated, tested and well characterized. Ready to use liquid formulation is used for the vaccine. The safety of the vaccine has been evaluated by conducting toxicology study in animals and Phase I safety trial in human adult and infants. The immunogenicity of the vaccine has been studied in Phase I/II safety-immunogenicity trial.

Results: Virus titers for all serotypes are adequate enough to formulate at competitive COGS. The vaccine is well characterized and found to be stable, safe and immunogenic.

Conclusion: The vaccine covers major serotypes worldwide and being all-in-one liquid formulation containing stabilizers and buffers, it has competitive advantage in the market. This vaccine will be the cost effective solution for preventing rotaviral diarrhea.

Biography

Lopa Adhikary, PhD is Program Leader at Shantha Biotechnics Pvt Ltd (Sanofi Company). She completed her PhD focusing on molecular aspect of host – virus interaction from Department of Biochemistry of Bose Institute, Kolkata and awarded PhD degree in 1998 and joined Post-doctoral research (Nov 1998 – Dec 2001) focusing on morphology and pathogenicity of negative stranded RNA virus in Department of Microbiology, Immunology & Molecular Genetics, School of Medicine, University of California, Los Angeles. She joined Medimmune in Jan 2002 as Research Scientist and took active participation in research work towards Flumist, a live attenuated flu vaccine. She came back to India to join Shantha in April 2005. Currently she is heading Rotavirus vaccine program.

Lopa.Adhikary@sanofi.com

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