Immunogenicity and Safety of the sanofi pasteur’s DTacP-IPV Combined Vaccine (TETRAXIM™) Given as a Booster Dose at 4 to 6 Years of Life in Children Previously Vaccinated with PENTAXIM™ in the Study E2I34

Phase IV, open, multicenter, one arm study

Final Clinical Study Report

Trial Code: E2I57
Development Phase: IV
Sponsor: Sanofi Pasteur SA
2, avenue Pont Pasteur, F-69367 Lyon cedex 07, France
Investigational Product: DTacP-IPV combined vaccine (Tetraxim™)
Form/Route: Liquid/ Intramuscular
Coordinating Investigators: Chitsanu PANCHAROEN, MD (Assoc Prof. of Pediatrics)
Chulalongkorn Hospital, Department of Pediatrics, Bangkok, Thailand
Tawee CHOTPITAYASUNONDH, MD (Assoc. Prof. of Pediatrics)
Queen Sirikit National Institute of Child Health, Bangkok, Thailand

Sponsor’s Responsible Medical Officer (Sponsor’s Signatory): Esteban ORTIZ, MD – Medical Director
Global Scientific and Medical Affairs, sanofi pasteur, France
Phone: 33 4 37 37 72 58  Fax: 33 4 37 37 71 71

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This trial was performed in compliance with Good Clinical Practice
1 Introduction

1.1 Background of the Investigational Product

The diphtheria, tetanus, and whole-cell pertussis (DTwP) vaccine was the first combined vaccine, containing pertussis. DTwP has been routinely administered as a combination with inactivated poliomyelitis virus vaccine (IPV) for more than 30 years in several countries. The reactogenic profile of whole-cell pertussis vaccines has led vaccine manufacturers to develop purified well-characterized acellular pertussis vaccines (aP), which have shown a better safety profile while maintaining the vaccine effectiveness.

Sanofi pasteur has developed several combination vaccines including a liquid combination of diphtheria, tetanus, acellular pertussis, and inactivated polio vaccine alone (DTacP-IPV) or to be used to reconstitute Act Haemophilus influenzae type b (ActHIB™) vaccine (DTacP-IPV//polyribosyl ribitol phosphate conjugated to tetanus protein [PRP~T]). The combined vaccines DTacP-IPV or DTacP-IPV//PRP~T have been licensed since 1997 in at least 35 countries (Europe and many other countries) under the trade name of TETRAVAC™ or TETRAXIM™ and PENTAVAC™ or PENTAXIM™ respectively. The approved indication is for 3-dose primary series (during the 1st year of life) and/or booster (during the 2nd year of life and at 4 to 6 years of age) vaccination.

The safety and immunogenicity of the sanofi pasteur’s DTacP-IPV or DTacP-IPV//PRP~T vaccines have been assessed in different clinical studies (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12).

In the clinical trials initiated by sanofi pasteur, more than 2000 infants received the sanofi pasteur’s DTacP-IPV combined vaccine as a 3-dose primary vaccination. The 3 lots consistency study of sanofi pasteur’s DTacP-IPV combined vaccine demonstrated that the vaccine is safe and immunogenic (clinical study E2I01294). In this study, sanofi pasteur’s DTacP-IPV vaccine was given as a single injection (in 3 lots consistency groups) according to a 3-dose primary vaccination schedule. The 3 lots consistency groups showed similar immunogenicity for each vaccine antigen (diphtheria, tetanus, two pertussis [pertussis toxoid (PT) and filamentous haemagglutinin (FHA)], and polio virus 1, 2 and 3), 1 month after the 3-dose primary vaccination was performed.

In a recent statement from World Health Organization (WHO) on pertussis vaccines a booster dose was recommended for children aged 1 to 6 years, preferably during the second year of life. This booster will improve protection following primary immunization. The timing of this booster should also provide an opportunity for catch-up vaccination and allow for the use of a combination vaccine containing both pertussis and Hib antigens. The booster should be given ≥6 months after the last primary dose. Completion of this schedule (primary series plus booster) is expected to ensure protection against pertussis for ≥6 years.

The sanofi pasteur’s DTacP-IPV combined vaccine also showed good immunogenicity and safety profile as compared to monovalent vaccines (1).

For further details on these studies, please refer to the protocol provided in Appendix 1.