## ANTIBODY PERSISTENCE AFTER PRIMARY AND BOOSTER DOSES OF A PENTAVALENT VACCINE AGAINST DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS, INACTIVATED POLIOVIRUS, HAEMOPHILUS INFLUENZAE TYPE B VACCINE AMONG THAI CHILDREN AT 18-19 MONTHS OF AGE

Tawee Chotpitayasunondh<sup>1</sup>, Usa Thisyakorn<sup>2</sup>, Chitsanu Pancharoen<sup>2</sup>, Sunate Chuenkitmongkol<sup>3</sup> and Esteban Ortiz<sup>4</sup>

<sup>1</sup>Queen Sirikit National Institute of Child Health, Bangkok; <sup>2</sup>King Chulalongkorn Memorial Hospital, Bangkok; <sup>3</sup>Sanofi Pasteur, Bangkok, Thailand; <sup>4</sup>Sanofi Pasteur, Lyon, France

Abstract. The World Health Organization recommends a booster dose of a pertussis-containing vaccine for children aged 1-6 years, preferably during the second year of life. This study assessed the immunogenicity and safety of a pentavalent combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and conjugated-Hib polysaccharide antigens, [(DTaP-IPV//PRP~T (Pentaxim<sup>®</sup>)], as a booster at 18-19 months of age. Participants had received primary doses of the same vaccine at 2, 4 and 6 months of age. Antibody concentrations were measured immediately before and one month after the booster dose. Adverse events were evaluated from parental reports. Geometric mean concentrations (GMCs) or titers (GMTs) decreased from post-primary to pre-booster vaccination; however, at least 94.4% of children had protective levels of anti-tetanus (≥0.01 IU/ml), antipoliovirus ( $\geq 8 1/dil$ ) and anti-PRP (Hib,  $\geq 0.15 \mu g/ml$ ) antibodies prior to the booster. Anti-diphtheria antibody titers  $\geq 0.01$  IU/ml were also observed in the majority of children pre-booster. One month after the booster, seroprotection rates were 99.4%for PRP ( $\geq 1.0 \,\mu$ g/ml), 95.0% for diphtheria ( $\geq 0.10 \,\text{IU/ml}$ ) and 100% for tetanus ( $\geq 0.1$ IU/ml) and poliovirus types 1, 2, 3 (≥8 1/dil). At least 93.1% of subjects had 4 fold post-booster increases in anti-pertussis antibody titers. GMCs increased from 14.0 to 307.3 EU/ml and from 13.9 to 271.9 EU/ml for anti-PT and anti-FHA, respectively. Anti-PRP GMC increased from 1.2 to 62.2 µg/ml. The booster was well tolerated. A booster dose during the second year of life was safe and induced a strong immune response, indicative of long-term protection.

**Keywords:** pentavalent combined vaccine, acellular pertussis, booster vaccination, inactivated polio vaccine, Hib-conjugate vaccine, safety, immunogenicity

Correspondence: Dr Sunate Chuenkitmongkol, Sanofi Pasteur, 87/2 CRC Tower, 23<sup>rd</sup> floor, All Seasons Place, Wireless Road, Lumpini, Patum Wan, Bangkok 10330, Thailand. E-mail: sunate.chuenkitmongkol@sanofipasteur.com