

**1089. Safety and Immunogenicity of DTaP-IPV (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Combined with Inactivated Poliovirus Vaccine) Compared to DAPTACEL<sup>®</sup> (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) + IPOL<sup>®</sup> (Poliovirus Vaccine Inactivated) as the 5th Dose in Children 4 to 6 Years of Age**

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**Session:** 128. Vaccines: Pertussis  
*Friday, October 10, 2014; 12:30 PM*

**Background.** A phase III multicenter controlled study assessed safety and immunogenicity of DTaP-IPV vaccine given as a 5<sup>th</sup> dose concomitantly with MMR and Varicella (V) vaccines compared to separately administered DAPTACEL and IPOL vaccines. DTaP-IPV is the liquid component of Pentacel used to reconstitute PRP-T. NCT01346293

**Methods.** Healthy 4-6 year-olds previously vaccinated with 4 doses of DAPTACEL and/or Pentacel were planned for randomization to 4 groups: 640 subjects to immunogenicity Groups 1 (DTaP - IPV + MMR +V) or Group 2 (DAPTACEL + IPOL - + MMR + V) (1:1 ratio) and 2700 subjects into safety Group 3 (DTaP - IPV + MMR + V) or Group 4 (DAPTACEL + IPOL + MMR + V) (8:1 ratio). Immunogenicity between Groups 1 and 2 was compared by: 1) Pertussis (PT, FHA, PRN, and FIM) booster responses and geometric mean concentrations (GMCs), 2) Diphtheria and tetanus booster responses and GMCs, 3) IPV booster responses and geometric

mean titers (GMTs). Noninferiority margins were 10% for booster responses and 0.67 for GMC or GMT ratio. Local and systemic reactions were compared between DTaP-IPV (Groups 1 + 3) and DAPTACEL + IPOL (Groups 2 + 4) recipients.

**Results.** 3372 subjects were randomized. 2743 received DTaP-IPV and 629 received DAPTACEL + IPOL. 97.4% of subjects completed all study activities up to day 28. DTaP-IPV was noninferior to DAPTACEL + IPOL as a fifth dose booster for all immunogenicity parameters evaluated:

- In the context of similar baseline titers, DTaP-IPV was associated with higher anti-pertussis GMCs than DAPTACEL. Booster response rates were also significantly higher for all pertussis antigen among DTaP-IPV recipients
- The GMCs and booster responses to diphtheria and tetanus antigens were non-inferior in those who received DTaP-IPV when compared to subjects who received DAPTACEL + IPOL
- The GMTs and booster responses to poliovirus antigens (types 1, 2, and 3) were noninferior in those receiving DTaP-IPV compared to those receiving DAPTACEL + IPOL
- Seroprotection rates for diphtheria, tetanus and polio were all at or close to 100%. Local and systemic reactions to vaccine were comparable among all vaccine groups.

**Conclusion.** DTaP-IPV was shown to be safe and immunogenic as a 5<sup>th</sup> dose booster in children 4-6 years of age. Study funded by Sanofi Pasteur.

**Disclosures.** M. Smith, Sanofi Pasteur: Investigator, Research support X. Sheng, Sanofi Pasteur: Employee, Salary E. Jordanov, Sanofi Pasteur: Employee, Salary P. Tsang, Sanofi Pasteur: Employee, Salary