Conclusion. There was no difference in risk for AEs or lab abnormalities between PISPZP Vaccine and NS, indicating that PISPZP Vaccine administered by DVI was extremely safe and well tolerated in 5-month- to 65-year-olds.

Disclosures. LW Preston Church, MD, FIDSA, Sanaria Inc. (Employee)

1242. Safety and Immunogenicity of Novel 24-Valent Pneumococcal Vaccine in Healthy Adults

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Session: P-57. New Vaccines

Background. Invasive pneumococcal disease (IPD) remains prevalent despite the use of conjugate vaccines over the past 20 years. Serotype replacement, limited efficacy for certain vaccine serotypes, and the incomplete coverage of disease in the elderly perpetuate the problem. Novel vaccines with broader serotype coverage are needed. To this end, a novel 24-valent pneumococcal vaccine, ASP3772, was developed based on a multiple antigen-presenting system (MAPS) platform. This platform that has been shown to achieve high affinity, noncovalent binding between bacteriophages and histidinemia to create a complex of 24 pneumococcal polyvalent vaccines and a fusion of two pneumococcal proteins.

Methods. Healthy adults aged 18-64 years were randomized into this active-controlled, observer-blinded, dose-escalation study to evaluate the safety, tolerability, and immunogenicity of ASP3772 at three dose levels compared to Prevnar13 (PCV13) (target 30 per dose group). The primary endpoints were safety and reactogenicity. Immunogenicity was evaluated secondarily by measuring serotype-specific immunoglobulin G (IgG) and opsonophagocytic activity (OPA).

Results. Ninety-three subjects received ASP3772 at 1 of 3 doses and 33 received PCV13. Safety and reactogenicity were similar between the ASP3772 and PCV13 arms. Most frequently reported local reactions were tenderness and pain after injection occurring within the first 2 days. Most frequent systemic reactions were fatigue, headache, and myalgia, without a clear dose response. Treatment-emergent adverse events were few and most were mild to moderate in severity. No clinically relevant abnormalities were observed in vital signs, ECGs, and laboratory parameters. Robust IgG and OPA responses were observed for serotypes shared with PCV13, as well as serotypes unique to ASP3772.

Conclusion. ASP3772 vaccine was safe, well tolerated in adults aged 18-64 years, and exhibited robust immunogenicity that extended beyond serotypes shared with PCV13.

Disclosures. Gurumadhi Chichili, PhD; Astellas Pharma Inc (Employee) Ronald Smulders, MD, PhD, Astellas Pharma Inc (Employee) Vicki Santos, n/a; Astellas Pharma Inc (Employee) Beth Cwyin, n/a, Astellas Pharma Inc (Employee) Laura Kovanda, n/a, Astellas Pharma Inc (Employee) Frank J. Malinsons, MD, PhD, Affinivax (Employee) Shite Sebastian, PhD, Affinivax (Employee) George R. Sibler, MD, Affinivax Inc (Consultant, Employee, Shareholder) Rick Malley, MD, Affinivax Inc (Board Member, Consultant, Employee)

1243. Semi-Quantitative Benefit-Risk Assessment for a New Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) in Individuals 2 Years of Age and Older

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Session: P-57. New Vaccines

Background. MenACYW-TT is a new quadrivalent meningococcal conjugate vaccine approved by the US FDA for use in individuals 2 years and older. We present the structured benefit-risk assessment conducted by Sanofi Pasteur in support of the initial biological license application for MenACYW-TT.

Methods. The safety and immunogenicity of MenACYW-TT in subjects ≥ 2 years was evaluated in 5 pivotal randomized, active-controlled clinical trials. Collectively, 4,919 subjects received either a single primary dose (n=4517) or a booster dose (n=402) of MenACYW-TT. A semi-quantitative framework was used to establish favorable and unfavorable effects of MenACYW-TT relative to comparators: MenACYW-CRM in children 2-9 years, MenACYW-D in adolescents 10-17 years, and MenACWY-D in adolescents 10-17 years and adults 18-55 years, and MPSV4 in older adults ≥ 56 years. Benefit outcome measures included vaccine seroresponse and seroprotection (titer ≥ 1:8) at D30 evaluated by serum bactericidal assay using human complement, for each serogroup. Risk outcome measures included rates of solicited injection site and systemic reactions (including grade 3 reactions) within 7 days after vaccination, and rates of serious adverse events within 6 months after vaccination. The differences in rates for MenACYW-TT vs comparator vaccines were calculated along with 95% confidence intervals.

Results. For all benefit criteria, and in all age groups, rate differences favored MenACYW-TT in meningococcal vaccine-naive individuals. Immune response differences were more pronounced for serogroup C. Differences showed favorable (seroconversion criteria) or comparable (seroprotection criteria) effects for MenACYW-TT in adolescents and adults previously primed with MenACYW-D or MenACYW-CRM. For the risk criteria, rate differences generally showed comparable effects between MenACYW-TT and MenACYW-D or MenACYW-CRM in children, adolescents and adults, while the rate differences for both solicited injection site and systemic reactions favored MPSV4 in older adults. The latter was possibly due to the use of a protein carrier in MenACYW-TT.

Conclusion. The benefit-risk profile of MenACYW-TT in individuals ≥ 2 years is considered favorable relative to comparator licensed vaccines.

Disclosures. David Neveu, MPPharm, Sanofi Pasteur (Employee) Marie-Laure Kurzinger, MSc, Sanofi (Employee) Aiying Chen, PhD, Sanofi Pasteur (Employee) Mandeep S. Dhingra, MD, Sanofi Pasteur (Employee)