1104. 13-Valent Pneumococcal Conjugate Vaccine (PCV13) Immunogenicity in the Community Acquired Pneumonia Immunization Trial In Adults (CAPiTA)

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Background. The CAPiTA study, which was a randomized, double-blind clinical trial in 84,496 participants 65 years of age and older in the Netherlands demonstrated efficacy against first episodes of vaccine type (VT) community acquired pneumonia and first episodes of VT-IPD. Results of the primary and secondary endpoints have been previously reported.

Methods. A subset of the subjects (2,011) was enrolled utilizing home based visits in a single region in the Netherlands. Blood samples for immunogenicity analysis were taken at baseline before vaccination, one month, 12 months and 24 months after vaccination. Serotype specific opsonophagocytic activity (OPA) titers and anticapsular polysaccharide immunoglobulin G (IgG) concentrations (μg/mL) were measured at each of these time points for all PCV13 serotypes and compared to placebo.

Results. For both OPA and IgG, there were significant increases in antibody levels for all serotypes one month after vaccination compared to before vaccination with PCV13. One month after vaccination the ratios for OPA geometric mean titers (GMTs) of PCV13 to placebo ranged from 4.4 (serotype 9V) to 62.6 (serotype 4); after 12 months the ratios ranged from 2.2 (serotype 9V) to 13.9 (serotype 4) and after 24 months from 1.6 (serotype 9V) to 8.0 (serotype 4).

One month after vaccination the ratios for IgG geometric mean concentrations (GMCs) of PCV13 to placebo ranged from 2.97 (serotype 3) to 12.12 (serotype 18C); after 12 months the ratios ranged from 1.66 (serotype 3) to 5.72 (serotype 18C) and after 24 months from 1.56 (serotype 3) to 4.76 (serotype 18C).

The ratios for both OPA GMTs and IgG GMCs in the age subgroups ≥65 to <70 years; ≥70 to <80 years and ≥80 years followed a similar pattern indicating that measurable antibody responses extended out at least two years after vaccination for all age groups.

Conclusion. The observed immune response data support the demonstrated efficacy of PCV13 against VT-CAP and VT-IPD in adults 65 years and older. Both binding IgG antibodies and functional OPA antibodies persisted at least two years after vaccination at levels above baseline. (Funded by Pfizer, Inc.; ClinicalTrials.govnumber NCT00744263.)

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