A PHASE 3 CLINICAL STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF V116 IN PNEUMOCOCCAL VACCINE-EXPERIENCED ADULTS 50 YEARS OF AGE OR OLDER (STRIDE-6)

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Background. Pneumococcal diseases (PD), including non-invasive disease such as pneumonia and invasive disease such as meningitis, cause considerable morbidity and mortality in adults. V116 is an investigational 21-valent pneumococcal conjugate vaccine (PCV) specifically designed to protect adults from pneumococcal serotypes responsible for the majority of residual PD. This phase 3 study evaluated safety, tolerability, and immunogenicity of V116 in pneumococcal vaccine-experienced adults ≥50 years.

Methods. A total of 712 generally healthy adults were vaccinated with a single dose of pneumococcal vaccine as follows: Cohort 1 previously received PPSV23 and were randomized 2:1 to receive V116 or PCV15, respectively; Cohort 2 previously received PCV13 and were randomized 2:1 to receive V116 or PPSV23, respectively; Cohort 3 previously received PPSV23+PCV13, PCV13+PPSV23, PCV15+PPSV23, or PCV15 and all received open-label V116. Immunogenicity was evaluated 30 days postvaccination using opsonophagocytic activity (OPA) geometric mean titers (GMTs) for all V116 serotypes. Safety was evaluated as the proportion of participants with adverse events (AEs).

Results. V116 was immunogenic across all 3 cohorts as assessed by serotype-specific OPA GMTs postvaccination for all 21 serotypes. V116 elicited comparable immune responses to serotypes shared with PCV15 (Cohort 1) or PPSV23 (Cohort 2), and higher immune responses to serotypes unique to V116 (Table 1). The proportions of participants with solicited AEs were generally comparable across cohorts (Figure 1).

Conclusions. V116 is well tolerated with a safety profile comparable to currently licensed pneumococcal vaccines, and generates functional immune responses to all V116 serotypes, regardless of prior pneumococcal vaccine received.