A Phase 3, randomised trial investigating the safety, tolerability and immunogenicity of V116, an adult-specific pneumococcal conjugate vaccine, compared with PPSV23, in adults ≥50 years of age (STRIDE-10)

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Background

Pneumococcal disease (PD) burden remains an unmet need in adults. V116 is an adult-specific pneumococcal conjugate vaccine containing prevalent serotypes associated with PD in adults from regions with established paediatric vaccination programmes. STRIDE-10 study evaluated the safety and immunogenicity of V116 compared to 23-valent pneumococcal polysaccharide vaccine (PPSV23) in pneumococcal vaccine-naïve adults aged ≥50 years.

Methods

Participants were randomised 1:1 to receive one dose of V116 or PPSV23. Pneumococcal serotype-specific opsonophagocytic activity (OPA) was measured at baseline (Day 1) and 30 days post-vaccination (Day 30). The primary objectives were to evaluate non-inferiority and superiority of immune responses for common and unique serotypes between V116 and PPSV23, respectively.

Results

In total, 1480 participants received either V116 (n=739) or PPSV23 (n=741). V116 was non-inferior to PPSV23 for the 12 common serotypes and was superior to PPSV23 for the 9 unique serotypes in V116, based on serotype-specific OPA geometric mean titres at Day 30 (Table 1). The proportion of participants with a ≥4-fold rise in OPA from baseline to Day 30 following V116 was superior to PPSV23 for 8 out of 9 unique serotypes (except serotype 15C; Table 2). AEs were reported in 61.0% of V116 and 56.8% of PPSV23 recipients.

Conclusions

V116 is non-inferior to PPSV23 for the common serotypes and superior to PPSV23 for the serotypes unique to V116 based on OPA GMTs at Day 30 and has a safety profile comparable to PPSV23. These findings support V116 as a novel population-specific vaccine for the prevention of PD in adults.

Key words: Vaccinology, clinical trials, pneumococcal

Table 1. Analysis of OPA GMTs at Day 30 after vaccination

Pneumococcal serotype	V116 (N=739)		PPSV23 (N=741)		GMT ratio† (V116/PPSV23) (95% CI)†,‡
	n	GMT†	n	GMT†	
Common serotypes in V116 and PPSV23 (non-inferiority analysis§)					
3	725	230.4	729	211.5	1.09 (0.96, 1.23)
7F	729	4876.7	732	3314.6	1.47 (1.29, 1.68)
8	730	3379.6	733	2882.1	1.17 (1.04, 1.32)
9N	728	7346.6	729	6545.9	1.12 (1.00, 1.26)
10A	725	4382.9	726	2818.7	1.55 (1.37, 1.77)