V116 Clinical Program Overview

For Media Background

V116 is an investigational, 21-valent pneumococcal conjugate vaccine in development for the prevention of invasive pneumococcal disease and pneumococcal pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20, 22F, 23A, 23B, 24F, 31, 33F, 35B in adults 18 years of age and older.

V116 remains under development and is not approved by regulatory authorities for use in any population. Visit www.clinicaltrials.gov for additional information about the V116 clinical development program.

Phase 3 Studies

The V116 Phase 3 clinical program includes eight studies designed to provide immunogenicity and safety data to support major market regulatory filings.

Study	Population	Objective	Enrollment*	Dosing
STRIDE-3 (V116-003)	Vaccine-naïve adults ≥18 years of age	To evaluate the safety, tolerability, and immunogenicity of V116 compared to PCV20.	2,664	1 dose of V116 or PCV20
STRIDE-4 (V116-004)	Vaccine-naïve adults 18-49 years of age	To evaluate the safety, tolerability, and immunogenicity for the lot consistency of V116 compared to PPSV23.	2,157	1 dose of V116 or PPSV23
STRIDE-5 (V116-005)	Adults ≥50 years of age	To evaluate the safety, tolerability, and immunogenicity of V116 when administered concomitantly with QIV compared with V116 administered sequentially with QIV.	1,080	1 dose of V116 and QIV followed by placebo on Day 30 or 1 dose of QIV and placebo followed by V116 on Day 30

STRIDE-6 (V116-006)	Adults ≥50 years of age who previously received a pneumococcal vaccine	To evaluate the safety, tolerability, and immunogenicity of V116 compared to other vaccines based on cohort design.	717	1 dose of V116 or PCV15 or PPSV23 (see study design for cohort details)
STRIDE-7 (V116-007)	Vaccine-naïve adults ≥18 years of age	To evaluate the safety, tolerability, and immunogenicity of V116 compared to PCV15 followed by PPSV23 in persons living with HIV.	313	1 dose of V116 (followed by placebo) or PCV15 (followed by PPSV23) at an 8-week interval
STRIDE-8 (V116-008)	Vaccine-naïve adults 18-64 years of age	To evaluate the safety, tolerability, and immunogenicity of V116 compared to PCV15 followed by PPSV23 in persons with increased risk of pneumococcal disease.	500	1 dose of V116 (followed by placebo) or PCV15 (followed by PPSV23) at an 8-week interval
STRIDE-9 (V116-009)	Vaccine-naïve Japanese adults ≥65 years of age	To evaluate the safety, tolerability, and immunogenicity of V116 compared to PPSV23.	450	1 dose of V116 or PPSV23
STRIDE-10 (V116-010)	Vaccine-naïve adults ≥50 years of age	To evaluate the safety, tolerability, and immunogenicity of V116 compared to PPSV23.	1,400	1 dose of V116 or PPSV23

**Enrollment numbers may vary.*

Phase 2 Studies

The V116 Phase 2 clinical program includes one study in adult populations. Click the trial below for more details.

- V116-001: A Phase 1/Phase 2 Study of Polyvalent Pneumococcal Conjugate Vaccine (V116) in Adults

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Glossary

- **PCV13:** Pneumococcal 13-valent conjugate vaccine is indicated in the U.S. for active immunization for the prevention of invasive disease in children 6 weeks through 17 years of age, and of pneumonia and invasive disease in adults 18 years of age and

older, caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. PCV13 is also indicated for active immunization for the prevention of otitis media in children 6 weeks through 5 years of age caused by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F; no otitis media efficacy data are available for serotypes 1, 3, 5, 6A, 7F, and 19A

- **PCV15:** Pneumococcal 15-valent conjugate vaccine is indicated in the U.S. for active immunization for the prevention of invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in individuals 6 weeks of age and older
- **PCV20:** Pneumococcal 20-valent conjugate vaccine is indicated in the U.S. for active immunization for the prevention of invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older. PCV20 is also indicated for the active immunization for the prevention of otitis media caused by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F in individuals 6 weeks through 5 years of age, and for active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 18 years of age and older. The indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F in individuals 18 years of age and older is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial
- **PPSV23:** Pneumococcal vaccine polyvalent, the currently available 23-valent pneumococcal polysaccharide vaccine, is indicated in the U.S. for active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F). It is approved for use in persons 50 years of age or older and persons aged ≥2 years who are at increased risk for pneumococcal disease
- **QIV:** Quadrivalent Influenza Vaccine

About Merck

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