V114 Clinical Program Overview

For Media Background

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V114 is an investigational 15-valent pneumococcal conjugate vaccine. The 15 serotypes of pneumococcus included in the vaccine are serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F. Serotypes 22F and 33F are not included in currently licensed pneumococcal conjugate vaccines and are commonly associated with invasive pneumococcal disease worldwide. V114 remains under development and is not approved by regulatory authorities for use in any population. Additional information about the V114 clinical development program can be found at www.clinicaltrials.gov.

By the Numbers:

18,631 Total Participants Enrolled*	**16** Phase III Studies	**7** Phase II Studies	Trial Sites in **36 Countries**

12 Studies in Adult Populations	**14** Studies in Pediatric Populations	**3** Studies in both Adult and Pediatric Populations	**5** Pivotal Studies	**5** Studies in Special Populations

**Does not include 5,880 participants targeted for enrollment in ongoing or new studies.*

Phase III Studies

The V114 Phase III clinical program includes 16 studies globally that are designed to evaluate safety, tolerability and immunogenicity across adult and pediatric populations, including special populations at increased risk for pneumococcal disease. Click here for a glossary of terms used.

Adult Populations

Pivotal

Study	Population	Objective	Enrollment	Dosing
PNEU-AGE (V114-019)	Healthy adults ≥50 years of age	To evaluate the safety and tolerability of V114 compared to PCV13 with respect to the proportion of participants with AEs	1,205	1 dose of V114 or PCV13

PNEU-TRUE (V114-020)		To evaluate the safety and tolerability of V114 and to compare the serotype-specific OPA GMTs at Day 30 across three different lots of V114	2,340	1 dose of V114 or PCV13

Special Populations

Study	Population	Objective	Enrollment	Dosing
PNEU-DAY (V114-017)	Adults 18-49 years of age at increased risk for pneumococcal disease	To evaluate the safety, tolerability and immunogenicity of V114 followed by administration of PPSV23 6 months later	1,515	1 dose of V114 or PCV13 followed by 1 dose of PPSV23 approximately 6 months later
PNEU-WAY (V114-018)	Adults ≥18 years of age with HIV	To evaluate the safety, tolerability and immunogenicity of V114 followed by administration of PPSV23 8 weeks later	302	1 dose of V114 or PCV13 followed by 1 dose of PPSV23 approximately 8 weeks later
PNEU-STEM (V114-022) **Pediatric portion included in "Pediatric Populations" section below*	Adults ≥18 years of age who previously underwent HSCT 90-180 days prior to randomization	To evaluate the safety, tolerability and immunogenicity of V114 after HSCT, and the safety and tolerability of PPSV23 administered 12 months following HSCT	250* **Target enrollment; study ongoing*	3 doses of V114 or PCV13 at Day 1, Day 30 and Day 60, followed by 1 dose of V114, PCV13, or PPSV23 12 months after HSCT

Additional Adult Studies

Study	Population	Objective	Enrollment	Dosing
PNEU-PATH (V114-016)	Healthy adults ≥50 years of age	To evaluate the safety, tolerability and immunogenicity of V114 followed by PPSV23; to evaluate immune response to the 15 serotypes contained in V114 when followed by administration of PPSV23, 12 months later	652	1 dose of V114 or PCV13 followed by 1 dose of PPSV23 approximately 1 year later
PNEU-FLU (V114-021)		To evaluate the safety and tolerability of V114 and QIV when administered concomitantly and non-concomitantly; to evaluate immune response to the 15 serotypes contained in V114 and the 4 influenza strains contained in QIV	1,200	1 dose of V114 administered concomitantly or non-concomitantly with QIV

Pediatric Populations

Pivotal

Study	Population	Objective	Enrollment	Dosing
PNEU-PED-EU-1 (V114-025)	Healthy infants 42-90 days of age	To evaluate the safety and immunogenicity (serotype-specific response rates and IgG GMCs) of V114 compared to PCV13 in healthy infants after 2-dose infant primary series and toddler dose	1,180	**Full Term Infants:** 2 primary doses of V114 or PCV13 at 2 and 4 months of age and a booster at 11-15 months of age **Preterm Infants:** 3 primary doses of V114 or PCV13 at 2, 3 and 4 months of age and a booster at 11-15 months of age
PNEU-PED-EU-2 (V114-026)	Healthy infants 70-111 days of age	To evaluate the safety and immunogenicity (serotype-specific response rates and IgG GMCs) of V114 compared to PCV13 in healthy infants after 2-dose infant primary series and toddler dose	1,180* **Target enrollment*	2 primary doses of V114 or PCV13 at 3 and 5 months of age and a booster at 12 months of age
PNEU-PED (V114-029)	Healthy infants 42-90 days of age	To evaluate the safety and immunogenicity (serotype-specific response rates and IgG GMCs) of V114 compared to PCV13 in healthy infants after 3-dose infant primary series and toddler dose	1,720	3 primary doses of V114 or PCV13 at 2, 4 and 6 months of age and a booster at 12-15 months of age

Special Populations

Study	Population	Objective	Enrollment	Dosing
PNEU-STEM (V114-022) **Adult portion included in "Adult Populations" section above*	Children 3 to <18 years of age who received HSCT	To evaluate the safety, tolerability and immunogenicity of V114 after HSCT, and the safety and tolerability of PPSV23 administered 12 months following HSCT	50 pediatric participants (3 to <18 years of age)* **Target enrollment; study ongoing*	3 doses of V114 or PCV13 at Day 1, Day 30 and Day 60, followed by 1 dose of V114, PCV13, or PPSV23 12 months after HSCT

PNEU-SICKLE (V114-023)	Children 5-17 years of age with sickle cell disease	To evaluate the safety and immunogenicity of V114 and PCV13 in children with sickle cell disease	100	1 dose of V114 or PCV13
PNEU-WAYPED (V114-030)	Children 6-17 years of age with HIV	To evaluate the safety and immunogenicity of V114 and PCV13 in children with HIV	400* **Target enrollment*	1 dose of V114 or PCV13 followed by 1 dose of PPSV23 8 weeks later

Additional Pediatric Studies

Study	Population	Objective	Enrollment	Dosing
PNEU-PLAN (V114-024)	Healthy infants, children and adolescents 7 months-17 years of age	To evaluate the safety, tolerability and immunogenicity of V114 as a catch-up regimen in pneumococcal vaccine-naïve children and those previously vaccinated with full or partial regimens of PCV10 or partial regimens or PCV13	600	**7 to 11 months of age:** 3 doses of V114 or PCV13 given approximately 8 weeks apart with the third dose given at ≥12 months of age **12 to 23 months of age:** 2 doses of V114 or PCV13 given 8 weeks apart **2 to 17 years of age:** 1 dose of V114 or PCV13
PNEU-DIRECTION (V114-027)	Healthy infants 42-90 days of age	To evaluate the safety, tolerability and immunogenicity of V114 and PCV13 in healthy infants switched from PCV13 to V114 during the U.S. PCV immunization schedule	900	3 primary doses of V114 or PCV13 at 2, 4 and 6 months of age and a booster at 12-15 months of age
PNEU-LINK (V114-031)		To evaluate the safety and tolerability of V114 and PCV13 in full-term infants (≥37 weeks gestational age), and evaluate the immunogenicity and safety of V114 and PCV13 in premature infants (<37 weeks gestational age) during a substudy analysis	2,400	3 primary doses of V114 or PCV13 at 2, 4 and 6 months of age and a booster at 12-15 months of age
PNEU-ERA (V114-032)		To evaluate the safety and efficacy of V114 against vaccine-type acute otitis media	4,000* **Target enrollment*	According to the local recommended schedule

Phase II Studies

The V114 Phase II clinical program includes 7 studies globally across adult and pediatric populations, including special populations; click each trial for more details.

V114-002: The Safety, Tolerability, and Immunogenicity Profiles of a Single Dose of V114, PPSV23, or PCV13 in Adults 50 Years of Age or Older
V114-003: A Study of Pneumococcal Conjugate Vaccine (V114) Compared to a Marketed Vaccine in Healthy Infants
V114-004: Safety, Tolerability and Immunogenicity of V114 in Healthy Adults and Infants
V114-005: A Study to Evaluate the Safety, Tolerability and Immunogenicity of V114 in Healthy Adults and Infants
V114-006: Safety, Tolerability, and Immunogenicity of Two Formulations of V114 in Healthy Adults 50 Years of Age or Older
V114-007: Safety, Tolerability, and Immunogenicity of V114 Compared to PCV13 in PPSV23-vaccinated Healthy Adults ≥65 Years of Age
V114-008: A Study to Evaluate the Safety, Tolerability, and Immunogenicity of Two Lots of V114 in Healthy Infants

Glossary:

AE: Adverse event

GMCs: Geometric mean concentrations

GMTs: Geometric mean titers

HSCT: Hematopoietic stem cell transplantation

IgG: Immunoglobulin G

OPA: Opsonophagocytic activity

PCV10: A 10-valent pneumococcal conjugate vaccine not approved or available in the U.S.

PCV13: Pneumococcal 13-valent conjugate vaccine [Diphtheria CRM_{197} protein], the currently available 13-valent pneumococcal conjugate vaccine. In the U.S., PCV13 is indicated 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 *Streptococcus 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. PCV13 does not protect against disease caused by S. pneumoniae serotypes that are not in the vaccine.

PPSV23: Pneumococcal vaccine polyvalent, the currently available 23-valent pneumococcal polysaccharide vaccine. In the U.S., PPSV23 is indicated 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. PPSV23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

QIV: Quadrivalent Influenza Vaccine

About Merck:
For more than 125 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.