

V503-049 FACT SHEET



A Phase 3, International, Multi-center, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Study the Efficacy, Immunogenicity, and Safety of the 9vHPV Vaccine, a Multivalent L1 Virus-Like Particle Vaccine, in the Prevention of Oral Persistent Infection with HPV Types 16, 18, 31, 33, 45, 52, or 58 in Adult Males, 20 to 45 Years of Age

STUDY POPULATION

About 6,000 men, age 20 to 45

- Have had at least one sexual partner during their life
- Have not already received an HPV vaccine
- Have no history of an HPV-related anal lesion or HPV-related head and neck cancer

Additional criteria apply.

STUDY DURATION

- Approximately 42 months
- About 10 study center visits

STUDY PURPOSE

This clinical research study will evaluate a study vaccine to see if it will lower the chance of getting a mouth infection caused by some types of Human Papillomavirus (HPV). These mouth infections may lead to cancers in the head and neck. The study will also test the safety of the study vaccine and see how the body handles the study vaccine.

STUDY VACCINE

The study vaccine, 9vHPV vaccine, also known as GARDASIL™9, is a vaccine (injection/shot) that is approved in many countries to help protect against anal and genital diseases caused by some types of HPV.

TREATMENT GROUPS

- Group 1: Three doses of the study vaccine.
- Group 2: Three doses of placebo. A placebo is an injection that looks like the study medication, but it does not contain any active medicine.

CONTACT INFORMATION

Name _____

Telephone Number _____