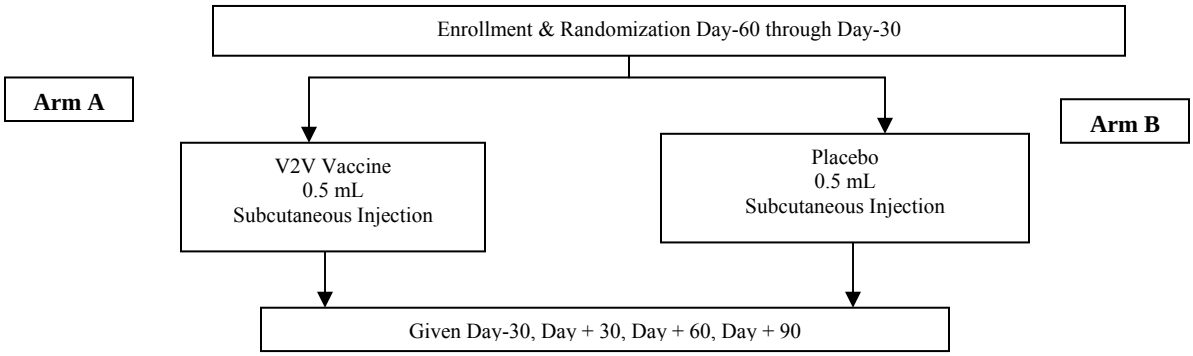
HO10414: A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multicenter Clinical Trial to Study the Safety, Tolerability, Efficacy, and Immunogenicity of V212 in Recipients of Autologous Hematopoietic Cell Transplants (HCTs)



Major INCLUSION Eligibility Criteria

- Patient is ≥18 years of age on day of signing informed consent.
- Patient has prior history of varicella, antibodies to VZV (documented prior to receipt of blood products), or residence in a country with endemic VZV infection for ≥30 years or if patient is 30 years old, attended primary or secondary school in a country with endemic VZV infection.
- Patient is scheduled to undergo autologous HCT for treatment of lymphoma or other indication, including any other malignancy or an indication that is not a malignancy within 60 days of enrollment.
- Patient is highly unlikely to conceive during the time period starting 2 weeks prior to enrollment through 6 months from last vaccination dose, as indicated by at least one "Yes" answer to the following questions.
  1)Patient is a male.
  2)Patient is a female of reproductive potential who agrees to remain abstinent or use (or have their partner use) adequate contraception during the time period starting 2 weeks prior to enrollment through 6 months from the last vaccination dose. Acceptable methods of birth control include use of hormonal contraceptives, intrauterine device (IUD), diaphragm with spermicide, contraceptive sponge, tubal ligation, condoms, or abstinence.
  3)Patient is a female who is not of reproductive potential. A female patient who is not of reproductive potential is defined as: one who has either (1) reached natural menopause (defined as 6 months of spontaneous amenorrhea with serum follicle stimulating hormone [FSH] levels in the postmenopausal range as determined by a laboratory, or 12 months of spontaneous amenorrhea), (2) post-surgical bilateral oophorectomy and/or hysterectomy, **or** (3) bilateral tubal ligation.
- All female patients of childbearing potential must have a negative serum or urine pregnancy test.
- Patient understands the study procedures and agrees to participate in the study by giving written informed consent.
- Patient is able to understand and complete study questionnaires.

Major EXCLUSION Eligibility Criteria

- Patient has a history of hypersensitivity reaction to any vaccine component, including gelatin or neomycin (a history of contact dermatitis to neomycin is not a criterion for study exclusion).
- Patient has a prior history of HZ within 1 year of enrollment.
- Patient has a prior history of receipt of any varicella or zoster vaccine.
- Patient has had more than 2 relapses of their underlying cancer. If the patient's underlying cancer is Hodgkin's lymphoma, more than 2 relapses are permitted.
- Patient is expected to undergo a tandem transplant procedure.
- Patient is expected to receive >6 months (>180 days) of prophylactic antiviral therapy post-HCT.
- Patient is pregnant or breastfeeding or expecting to conceive within the period of 2 weeks prior to enrollment through 6 months from last vaccination dose.
- Patient has received a live virus vaccine or is scheduled to receive a live virus vaccine in the period from 4 weeks prior to Dose 1 through 28 days Postdose 4.
- Patient has received an inactivated vaccine or is scheduled to receive an inactivated vaccine in the period between 7 days prior to and 28 days following Doses 1 through 4.
- Patient is unlikely to adhere to the study procedures or keep appointments.
- Any other reason that, in the opinion of the investigator, might interfere with the evaluation required by the study.

Coordinator: Jess Matthias 3-4511 / pager 5167