A Safety and Immunogenicity Study of CHIKV VLP Vaccine in Children.

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 year to 11 years old
Healthy Volunteers: This study is also accepting healthy volunteers
Inclusion Criteria:

1. Males or females between 1 and <12 years of age at Day 1 (day of vaccination). Note: Screening should only occur in the active/open cohorts. Please see Section 6.1 for details
2. Body weight ≥6.5 kg.
3. In general good health, in the opinion of the investigator, based on medical history and physical examination.
4. Able and willing to provide informed assent for study participation and primary caregiver is able and willing to provide informed consent for study participation, in accordance with the Institutional Review Board (IRB)/Independent Ethics Committee (IEC) determination and applicable federal and local regulations and guidelines.
5. Able and willing to complete all scheduled visits and comply with all study procedures.

Exclusion Criteria:

1. Participation or planned participation in an investigational clinical study (eg, vaccine, drug) within 30 days before Day 1 and for the duration of the study. Note: Participation in an observational study or follow-up phase of a study may be allowed; these instances should be discussed with the sponsor's medical monitor and written agreement obtained prior to enrollment.
2. Current acute illness, with or without fever.
3. Current or recent CHIKV infection indicated by positive immunoglobulin M (IgM) and negative immunoglobulin G (IgG) rapid diagnostic test (RDT) results at screening in the Philippines only; participants in the US will not be tested using the RDT.
4. History of any known or suspected allergy or history of anaphylaxis to any component of the investigational product.
5. History of any known congenital or acquired immunodeficiency or immunosuppressive condition that could impact response to vaccination.
6. Prior receipt or anticipated use of systemic immunomodulatory or immunosuppressive medications from 180 days prior to screening through Day 22. Note: Systemic corticosteroid use at a dose or equivalent dose of 20 mg or greater (≥0.5 mg/kg for children <40 kg) of prednisone for 14 consecutive days or more within 90 days of screening through Day 22 is exclusionary. The use of inhaled, intranasal, topical, or ocular steroids is allowed.
7. Receipt or anticipated receipt of immunoglobulin from 180 days prior to screening through the duration of the study.
8. Any administration or planned administration of:

- A licensed live attenuated vaccine within 28 days before administration of investigational product and until Visit 2 (Day 15 or 22, as applicable) has occurred.
- Other licensed (not live) vaccine within 14 days before administration of investigational product and until Visit 2 (Day 15 or 22, as applicable) has occurred.
- Another licensed or investigational CHIKV vaccine.
    1. Known infection with human immunodeficiency virus, hepatitis C virus (HCV), or hepatitis B virus. Note: Positive anti-HCV antibodies and negative HCV polymerase chain reaction would NOT be exclusionary. Polymerase chain reaction testing will not be performed as part of this protocol.
    2. Bleeding disorder or receipt of anticoagulants in the 21 days before Day 1, contraindicating intramuscular vaccination, as judged by the investigator.
    3. Receipt or anticipated receipt of blood products from 90 days before Day 1 through the duration of the study.
    4. Onset of menarche prior to study vaccination.
    5. Planned medical or surgical procedure that could adversely impact the participant's participation or the conduct of the study.
    6. Identified as an immediate family member of the investigator or employee with direct involvement in the study. Bavarian Nordic staff members and their families, contractors, agents, business partners, and anyone with a financial interest in the outcome of the study.
    7. Any other medical condition, including severe malnutrition, that, in the opinion of the investigator, could adversely impact the participant's participation or conduct of the study.

Conditions & Interventions

Interventions:
BIOLOGICAL: CHIKV VLP vaccine, BIOLOGICAL: Placebo
Conditions:
Chikungunya Virus
Keywords:
Chikungunya, PXVX0317, CHIKV VLP, vaccine, immunogenicity, VIMKUNYA, children

More Information

Description:
The goal of this multi-center, randomized, double-blind, placebo-controlled study is to evaluate the safety and immunogenicity of CHIKV VLP Vaccine in children 1 to \<12 years of age.

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Phase: PHASE3
IRB Number:
System ID: NCT07003984
