International country feasibility for the implementation of a Covid-19 Vaccine Trial

Preliminary Inclusion Criteria

Participants are eligible to be included in the study only if all the following criteria apply:

1. Adults, ≥ 18 years of age at time of consent, who are at high risk of SARS-CoV-2 infection, defined as adults whose locations or circumstances put them at appreciable risk of exposure to SARS-CoV-2 and COVID-19.
2. Understands and agrees to comply with the study procedures and provides written informed consent.
3. Able to comply with study procedures based on the assessment of the Investigator.
4. Female participants of nonchildbearing potential may be enrolled in the study.
5. Nonchildbearing potential is defined as surgically sterile (history of bilateral tubal ligation, bilateral oophorectomy, hysterectomy) or postmenopausal (defined as amenorrhea for ≥ 12 consecutive months prior to Screening without an alternative medical cause). A follicle-stimulating hormone (FSH) level may be measured at the discretion of the investigator to confirm postmenopausal status (see additional information in Appendix 11.3).
6. Female participants of childbearing potential may be enrolled in the study if the participant fulfills all the following criteria:
    - Has a negative pregnancy test at Screening and on the day of the first dose (Day 1).
    - Has practiced adequate contraception or has abstained from all activities that could
7. result in pregnancy for at least 28 days prior to the first dose (Day 1).
    - Has agreed to continue adequate contraception through 3 months following the
8. second dose (Day 29).
    - Is not currently breastfeeding.
    - Adequate female contraception is defined as consistent and correct use of a Food and Drug Administration (FDA) approved contraceptive method in accordance with the product label. For example:
    - Barrier method (such as condoms, diaphragm, or cervical cap) used in conjunction with spermicide
    - Intrauterine device
    - Prescription hormonal contraceptive taken or administered via oral (pill), transdermal (patch), subdermal, or IM route
        - Sterilization of a female participant's monogamous male partner prior to entry into the study
        - Note: periodic abstinence (eg, calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.

9. Healthy adults or adults with pre-existing medical conditions who are in stable condition.
10. A stable medical condition is defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment.

Preliminary Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

1. Is acutely ill or febrile 72 hours prior to or at Screening. Fever is defined as a body temperature ≥ 38.0°C/100.4°F. Participants meeting this criterion may be rescheduled within the relevant window periods. Afebrile participants with minor illnesses can be enrolled at the discretion of the investigator.
2. Is pregnant or breastfeeding.
3. Known history of SARS-CoV-2 infection.
4. Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19.
5. Demonstrated inability to comply with the study procedures.
6. An immediate family member or household member of this study's personnel.
7. Known or suspected allergy or history of anaphylaxis, urticaria, or other significant adverse reaction to the vaccine or its excipients.
8. Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy.
9. Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP).
11. Has participated in an interventional clinical study within 28 days prior to the day of enrollment.
12. Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections (HIVpositive participants with CD4 count ≥350 cells/mm3 and an undetectable HIV viral load within the past year [low level variations from 50-500 viral copies which do not lead to changes in antiretroviral therapy [ART] are permitted]).
13. Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent).

14. Has received systemic immunoglobulins or blood products within 3 months prior to the day of screening.^
15. Has donated ≥ 450 mL of blood products within 28 days prior to Screening