Study of recombinant protein vaccines with adjuvant as a primary series and as a booster dose against COVID-19 in adults 18 years of age and older (VAT00002)





VACCINES FORMULATION

- CoV2 preS dTM (recombinant) with AS03 adjuvant
- Monovalent (D614) adjuvanted, Monovalent (B.1.351) with or without AS03 adjuvant and bivalent (D614 + B.1.351) adjuvanted formulations
- Intramuscular injection; vaccine storage between 2 8°C



STUDY TYPE

Phase 2/3 randomized multi-center study, double-blind and open label cohorts

PRIMARY SERIES

INITIAL COHORT

ADDITIONAL COHORTS

BOOSTER DOSES

Endpoints



 To assess the immunogenicity (neutralizing antibody titers) after primary series vaccination in SARS-CoV-2-naïve adults

· To assess the safety profile

· To assess the immunogenicity of a booster dose of monovalent or bivalent SARS-CoV-2 vaccine given to adults previously vaccinated with an authorized/ approved COVID-19 vaccine (D614 strain)

Objectives/ success criteria



- To define the optimal dose to move into phase 3
- To demonstrate a non-inferiority of immune response with two doses of monovalent (B.1.351)-AS03 or bivalent (D614 + B.1.351)-AS03 SARS-CoV-2 vaccine compared to the response induced by monovalent (D614)-AS03 vaccine
- To demonstrate a non-inferiority of immune response after a single booster dose compared to a priming series, and a superiority of immune response compared to that observed immediately before booster

DESIGN



>5000 participants including subjects who completed a COVID primo-vaccination schedule authorized/conditionally approved COVID-19 vaccine (booster dose cohorts) and the SARS-CoV-2 naïve participants (initial cohort and supplemental cohorts)

INITIAL COHORT



SARS-CoV2 naïve adults

5µg, 10µg, and 15µg

Monovalent (D614)-AS03

0 **US and Honduras**

ADDITIONAL

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completed the primary series

Single booster dose

Monovalent (D614)-AS03 Bivalent (D614 + B.1.351)-AS03

Monovalent (B.1.351) with or without AS03 adjuvant

COHORTS

SUPPLEMENTAL

18-55 years old

2 doses

Monovalent (D614)-AS03 Monovalent (B.1.351)-AS03

Bivalent (D614 + B.1.351)-AS03

INCLUSION CRITERIA



- 18 years old or older
- Able to attend all trial visits and comply with all study procedures
- **BOOSTER DOSE COHORTS**: Participants who received a complete primary vaccination series with an authorized/ conditionally approved COVID-19 vaccine (mRNA or adenovirus-vectored) or participants from VAT00002 initial cohort (primed with the protein subunit candidate between 4 to 10 months prior to inclusion

EXCLUSION CRITERIA



- Individuals who received any vaccine in the within 30 days preceding the first study vaccination, or following the second injection (except influenza vaccine)
- Pregnant of breastfeeding women







