UC San Diego Health

COVID-19 Vaccine Update

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COVID-19 Vaccines in Persons with HIV

- Pfizer, Moderna, Janssen and AstraZeneca all enrolled persons with HIV
  - Overall – relatively small numbers (200-300 out of 30,000 to 40,000)
  - Participants were in general stable with CD4 >200-300 and durably suppressed
  - Pfizer analysis (NEJM) did not include the 196 people with HIV
  - Moderna enrolled 176 people with HIV – symptomatic COVID observed in 1 placebo recipient and none who received vaccine. No unusual safety concerns.
  - AstraZeneca UK/Brazil analysis (Lancet) did not include the 160 people with HIV
- It is possible that people with HIV may not respond as well to COVID vaccines – if the vaccine elicits a weaker immune response.
- However, people with HIV may also be at greater risk for severe COVID-19 and thus can receive vaccination.
  - Safety and efficacy data specific to this group are not yet available

mRNA Activity Against Circulating Variants

- Vaccinee serum samples assayed for neutralization against B.1.1.7, B.1.351, and WT viruses
  - No loss of NAb activity against B.1.1.7
  - Every sample had decreased activity against B.1.351
    - 12.4-fold for Moderna
    - 10.3-fold for Pfizer
- Vaccinee serum tested against mutant pseudovirus
  - No single mutation in B.1.1.7 had appreciable impact on neutralizing activity of vaccinee sera
  - Major contributor to neut resistance of B.1.351 is E484K – a RBD mutation in an immunodominant epitope recognized by all vaccinees studied

Wang P, et al. bioRxiv preprint doi: https://doi.org/10.1101/2021.01.25.428137

Janssen Phase III Interim Analysis (1/29/2021)

28 Days after vaccination:

- VE **85%** in preventing severe COVID disease in all geographies.
  - 100% protection against COVID-related hospitalization and death
  - Protection generally consistent across race and age groups (34% >60 yrs), and across all variants and regions studied.
- In US, **VE 72%** in preventing moderate and severe disease (66% avg globally).
- **VE 89%** against severe disease caused by the South African B.1.351 Variant.
  - VE 57% against any symptomatic COVID-19 caused by B.1.351
- Vaccine well tolerated with no notable safety signals
  - Older (age ≥ 65) vs. younger (18-64) showed lower reactogenicity
  - Most frequent AEs were HA, chills, fatigue, and myalgias (all 1.5-2.1%)

https://www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-endpoints-in-interim-analysis-of-its-phase-3-ensemble-trial

Janssen (J&J) Timeline

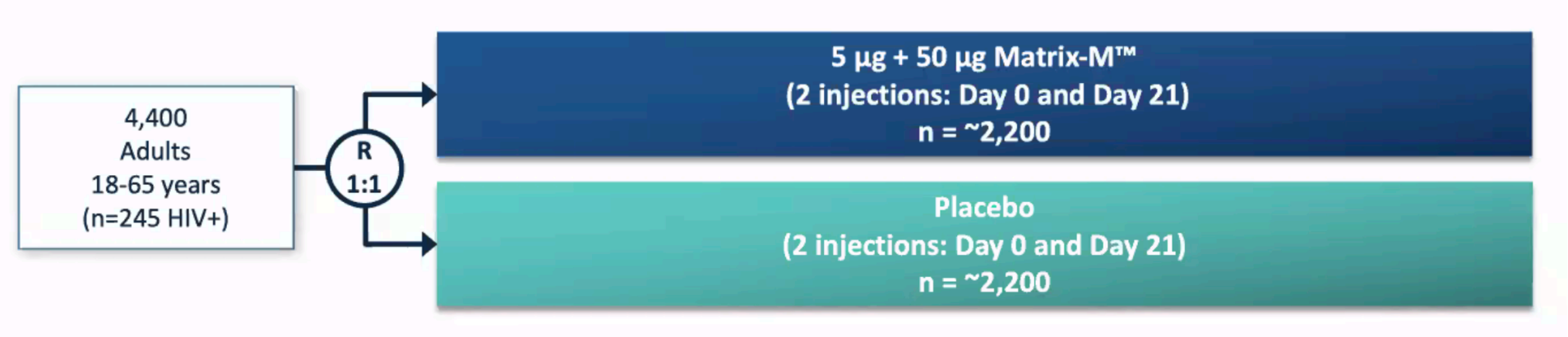
- Phase 3 Interim Analysis: Jan 29, 2021
- FDA submission for EUA: Feb 4, 2021
- FDA's Vaccines and Related Biologics Product Advisory Committee (VRBPAC): Feb 26, 2021
- Anticipate EUA approval early March

Novavax: UK Phase 3 Results

- Enrolled >15,000 adults 18-84 (27% > 65 yrs)
- Design: Participants randomized 1:1 to receive 2 doses NVX-CoV2373 or placebo (Day 0 and 21)
- Primary Endpoint: PCR confirmed, symptomatic COVID-19, ≥7 days after 2nd vaccination in participants seronegative (to SARS-CoV-2) at baseline
  - **VE 89.3%** (75.2-95.4) in preventing symptomatic COVID (61 of 62 cases were mild/mod)
  - **VE 95.6%** against the original Wuhan strain and **85.6%** against the UK variant strain (>50% of cases were 501Y.V1/ B.1.1.7)

https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3

Novavax: South African Phase 2b Clinical Trial



- Enrolled >4,400 participants Aug 2020 – mid Jan 2021 (B.1.351 increased from <5% to ~80%)
- 44 COVID-19 events to date – 93% of those sequenced (25/27) are 501Y.V2/B.1.351
- **VE 60%** (19.9-80.1) for prevention of mild, mod and severe disease in participants without HIV, **49.4%** (6.1-72.8) among participants with and without HIV
- Baseline seropositive for SARS-CoV-2: 30.2% (vaccine ≈ placebo, not included in primary analysis)
  - Attack rate was equal among seropositive and seronegative placebo recipients (dose 1 & 2)
  - No evidence of resistance from infection with previous recovered COVID infection

https://ir.novavax.com/news-releases/news-release-details/novavax-covid-19-vaccine-demonstrates-893-efficacy-uk-phase-3

WHO Grants Emergency Authorization for AstraZeneca (Feb 15, 2021)

- WHO's Strategic Advisory Group of Experts on Immunization (SAGE):
  - Assessed the quality, safety and efficacy data, risk management plans and programmatic suitability, such as cold chain requirements
  - The newly approved vaccines are produced by AstraZeneca-SKBio in South Korea and the Serum Institute of India
  - Recommended dosing interval of 8-12 weeks
  - AZ currently approved in >50 countries, including Britain, India, Argentina, Australia, and Mexico.
    - Including use in countries where new variants prevalent (i.e., B.1.351)

https://thehill.com/policy/healthcare/public-global-health/538887-who-grants-emergency-authorization-for-astrazeneca