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Moderna COVID-19 Vaccine (mRNA-1273)

NAIIS COVID-19 Vaccine webinar - January 29, 2021

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Moderna COVID-19 Vaccine: Indication & Safety Information

- **Authorized Use in the United States:**
  - The Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.
- **Important Safety Information:**
  - Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine.
  - Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).
  - Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.
  - The Moderna COVID-19 Vaccine may not protect all vaccine recipients.
  - Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site.
  - Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.
  - There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.
  - Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.
  - Vaccination providers must complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words " Moderna COVID- 19 Vaccine EUA " in the description section of the report.

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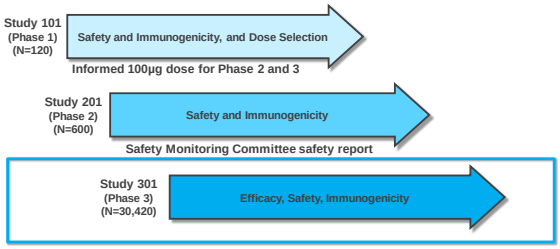
mRNA-1273 Full Development Program Supports the 100-µg Dose



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Study 301: Post Hoc Analysis of Efficacy of mRNA-1273 by Time Periods

mITT Population – Primary Efficacy Analysis

	mRNA-1273 N=14,550		Placebo N=14,598		
Start of Case Counting	n	Incidence rate/ 1000 person-years	n	Incidence rate/ 1000 person-years	VE % (95% CI)
Dose 1 to Dose 2	7	5.8	46	38.0	84.7% (65.8%, 94.2%)
Dose 2 to <14 days after Dose 2	0	0	19	11.4	100% (78.6%, NE)
14 days or more after Dose 2	12	3.7	204	63.3	94.2% (90.0%, 97.0%)

Vaccine Efficacy estimates have been adjusted for person-years of follow-up

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Study 301: Summary of Asymptomatic SARS-CoV-2 Infections as Measured by Scheduled NP Swabs Prior to 2nd Dose

Per Protocol – Primary Efficacy Analysis

	mRNA-1273 N=14,134		Placebo N=14,073	
RT-PCR Results and Clinical Symptoms	n	%	N	%
Positive RT-PCR and no documented COVID-19 symptoms between 1st dose and 2nd dose	14	0.1%	38	0.3%

Data suggestive of efficacy for prevention of asymptomatic infection

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Moderna Committed to Collecting Additional Data in a Broader Range of Patients

- Pediatric studies ongoing
- National Cancer Institute collaboration
- Post-authorization active surveillance and safety study
- Global pregnancy registry under development
- Post-authorization effectiveness study under development
- Safety and immunogenicity in solid organ transplant patients

Moderna will continue to collaborate with NIH, FDA, CDC and other agencies

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Thank you to our collaborators, investigators and subjects

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- Division of Microbiology and Infectious Diseases, NIAID
- Vaccine Research Center (VRC), NIAID
- Coalition for Epidemic Preparedness Innovation
- Principal Investigators, Drs. Lisa Jackson (Kaiser Permanente Washington), Evan Anderson (Emory University School of Medicine), Nadine Rouphael (Emory University School of Medicine), Alicia Widge (VRC)
- The Emmes Company
- Denison Lab, Vanderbilt University
- Baric Lab, University of North Carolina
- Suthar Lab, Emory University
- Vaccine Immunology Program, NIAID
- Study sites, investigators and subjects

P201

- BARDA
- Study sites, investigators, and subjects

COVE Study (P301)

- BARDA
- Operation Warp Speed
- NIAID and the COVID-19 Prevention Network
- Members of Diversity and Inclusion Panel
- Principal Investigators, Drs. Brandon Essink (Meridian Clinical Research), Lindsey Baden (Brigham and Women's Hospital), Hana El Sahly (Baylor College of Medicine)
- Study sites, investigators, and subjects

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