

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA)

MODERNA COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5)

BOOSTER DOSE FOR 18 YEARS OF AGE AND OLDER

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), for active immunization to prevent COVID-19 in individuals 18 years of age and older.

Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is hereafter referred to as Moderna COVID-19 Vaccine, Bivalent.

Moderna COVID-19 Vaccine, Bivalent is authorized for use in individuals 18 years of age and older as a single booster dose administered at least 2 months after either:

- completion of primary vaccination with any authorized or approved monovalent¹ COVID-19 vaccine, or
- receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

Moderna COVID-19 Vaccine, Bivalent is supplied in a multiple-dose vial with a dark blue cap and a label with a gray border.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of myocarditis, cases of pericarditis, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of Moderna COVID-19 Vaccine, Bivalent. See “MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE, BIVALENT, ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

Moderna COVID-19 Vaccine, Bivalent is a suspension for intramuscular injection.

¹ Monovalent refers to any authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

A single booster dose (0.5 mL) of Moderna COVID-19 Vaccine, Bivalent may be administered at least 2 months after completion of primary vaccination or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine, Bivalent for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

The information in this Fact Sheet supersedes the information on the vial and carton labels.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Frozen Storage

Store frozen between -50°C to -15°C (-58°F to 5°F).

Storage after Thawing

- Storage at 2°C to 8°C (36°F to 46°F):
 - Vials may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.
 - Vials should be discarded 12 hours after the first puncture.
- Storage at 8°C to 25°C (46°F to 77°F):
 - Vials may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours.
 - Vials should be discarded 12 hours after the first puncture.
 - Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.

Do not refreeze once thawed.

Thawed vials can be handled in room light conditions.

Transportation of Thawed Vials at 2°C to 8°C (36°F to 46°F)

If transport at -50°C to -15°C (-58°F to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2°C to 8°C (36°F to 46°F) when shipped using shipping containers which have been qualified to maintain 2°C to 8°C (36°F to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2°C to 8°C (36°F to 46°F), vials should not be refrozen and should be stored at 2°C to 8°C (36°F to 46°F) until use.

Dosing and Schedule

A single booster dose (0.5 mL) of Moderna COVID-19 Vaccine, Bivalent may be administered at least 2 months after completion of primary vaccination or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

Preparation for Administration

- Moderna COVID-19 Vaccine, Bivalent is supplied as a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Verify that the vial label states Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5).
- Thaw each vial before use following the instructions below.

Thawing Instructions for Moderna COVID-19 Vaccine, Bivalent

Thaw in Refrigerator	Thaw at Room Temperature
Thaw between 2°C to 8°C (36°F to 46°F) for 2 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 15°C to 25°C (59°F to 77°F) for 45 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- Moderna COVID-19 Vaccine, Bivalent is a white to off-white suspension. It may contain white or translucent product-related particulates. Do not administer if vaccine is discolored or contains other particulate matter.
- A booster dose for individuals 18 years of age and older is 0.5 mL.
- Each multiple dose vial contains 5 booster doses of 0.5 mL.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- After the first 0.5 mL booster dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine, Bivalent vial label. Discard vial after 12 hours. Do not refreeze.

Administration

Administer Moderna COVID-19 Vaccine, Bivalent intramuscularly.

CONTRAINDICATION

Do not administer Moderna COVID-19 Vaccine, Bivalent to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of Moderna COVID-19 Vaccine, Bivalent (*see Full EUA Prescribing Information*).

WARNINGS**Management of Acute Allergic Reactions**

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Moderna COVID-19 Vaccine, Bivalent.

Monitor Moderna COVID-19 Vaccine, Bivalent recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

Myocarditis and Pericarditis

Postmarketing safety data with Moderna COVID-19 Vaccine are relevant to Moderna COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Moderna COVID-19 Vaccine, the observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

Some, but not all, observational analyses of postmarketing data suggest that there may be an increased risk of myocarditis and pericarditis in males under 40 years of age following the second dose of Moderna COVID-19 Vaccine primary series relative to other authorized or approved mRNA COVID-19 vaccines.

The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Moderna COVID-19 Vaccine, Bivalent.

Limitations of Vaccine Effectiveness

Moderna COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

ADVERSE REACTIONS

The safety of a booster dose of Moderna COVID-19 Vaccine, Bivalent is based on:

- safety data from a clinical study which evaluated a booster dose of Moderna's bivalent COVID-19 vaccine (Original and Omicron BA.1), not authorized or approved in the U.S., hereafter referred to as bivalent vaccine (Original and Omicron BA.1),
- safety data from clinical trials which evaluated primary and booster vaccination with Moderna COVID-19 Vaccine², and
- postmarketing safety data with Moderna COVID-19 Vaccine

The safety data accrued with the bivalent vaccine (Original and Omicron BA.1) and with Moderna COVID-19 Vaccine are relevant to Moderna COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process. The bivalent vaccine (Original and Omicron BA.1) contained 25 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized S-glycoprotein of SARS-CoV-2 Wuhan-Hu-1 strain (Original) and 25 mcg of mRNA encoding the S-glycoprotein of SARS-CoV-2 Omicron variant lineage BA.1, for a total of 50 mcg mRNA per dose. This is the same total quantity of mRNA per dose as a dose of Moderna COVID-19 Vaccine, Bivalent and as a booster dose of Moderna COVID-19 Vaccine (previously authorized for booster vaccination in individuals 18 years of age and older), and half the total quantity of mRNA as a primary series dose of Moderna COVID-19 Vaccine for individuals 12 years of age and older.

Adverse Reactions in Clinical Trials

Adverse reactions reported in clinical trials following administration of bivalent vaccine (Original and Omicron BA.1) include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, axillary swelling/tenderness, nausea/vomiting, erythema at the injection site, swelling at the injection site, and fever. (*See Full EUA Prescribing Information*)

Adverse Reactions in Post-Authorization Experience of Moderna COVID-19 Vaccine

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with post-authorization use of Moderna COVID-19 Vaccine, Bivalent.

² Moderna COVID-19 Vaccine is a monovalent vaccine that encodes the spike protein of only the Original SARS-CoV-2.

USE WITH OTHER VACCINES

There is no information on the co-administration of Moderna COVID-19 Vaccine, Bivalent with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS” (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving each dose of Moderna COVID-19 Vaccine, Bivalent, including:

- FDA has authorized the emergency use of Moderna COVID-19 Vaccine, Bivalent, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Moderna COVID-19 Vaccine, Bivalent.
- The significant known and potential risks and benefits of Moderna COVID-19 Vaccine, Bivalent, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are evaluating the use of Moderna COVID-19 Vaccine, Bivalent to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver.

Provide the **v-safe** information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in **v-safe**. **V-safe** is a voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE, BIVALENT ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Moderna COVID-19 Vaccine, Bivalent, the following items are required. Use of unapproved Moderna COVID-19 Vaccine, Bivalent for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Moderna COVID-19 Vaccine, Bivalent is authorized for use in individuals 18 years of age and older.
2. The vaccination provider must communicate to the individual receiving Moderna COVID-19 Vaccine, Bivalent or their caregiver information consistent with the “VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS” prior to the individual receiving the Moderna COVID-19 Vaccine, Bivalent.

3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
 - vaccine administration errors whether or not associated with an adverse event,
 - serious adverse events* (irrespective of attribution to vaccination),
 - cases of myocarditis,
 - cases of pericarditis,
 - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
 - cases of COVID-19 that result in hospitalization or death.

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, Bivalent EUA” in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, cases of myocarditis, cases of pericarditis, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of Moderna COVID-19 Vaccine, Bivalent to recipients.

*Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine, Bivalent Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
<p data-bbox="212 527 755 554">www.modernatx.com/covid19vaccine-eua</p> 	<p data-bbox="987 527 1227 590">1-866-MODERNA (1-866-663-3762)</p>

AVAILABLE ALTERNATIVES

There may be clinical trials or availability under EUA of other COVID-19 vaccines for use as a booster dose, including bivalent vaccines that contain or encode the spike protein of the Omicron variant of SARS-CoV-2.

FEDERAL COVID-19 VACCINATION PROGRAM

This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see <https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html>.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine Bivalent, for active immunization to prevent COVID-19.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

For the authorized uses, although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that Moderna COVID-19 Vaccine, Bivalent may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for Moderna COVID-19 Vaccine, Bivalent will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization, visit FDA at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

COUNTERMEASURES INJURY COMPENSATION PROGRAM

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit <http://www.hrsa.gov/cicp>, email cicp@hrsa.gov, or call: 1-855-266-2427.

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END SHORT VERSION FACT SHEET
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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE, BIVALENT (ORIGINAL ANDOMICRON BA.4/BA.5)

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is authorized for use under an Emergency Use Authorization (EUA) 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.

This EUA Prescribing Information pertains only to Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Moderna COVID-19 Vaccine, Bivalent.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

The storage, preparation, and administration information in this EUA Prescribing Information apply to Moderna COVID-19 Vaccine, Bivalent for individuals 18 years of age and older, which is supplied in a multiple-dose vial with a dark blue cap and a label with a gray border.

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2.1 Preparation for Administration

- Moderna COVID-19 Vaccine, Bivalent is supplied as a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Verify that the vial label states Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5).
- Thaw each vial before use following the instructions below.

Thawing Instructions for Moderna COVID-19 Vaccine, Bivalent

Thaw in Refrigerator	Thaw at Room Temperature
Thaw between 2°C to 8°C (36°F to 46°F) for 2 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 15°C to 25°C (59°F to 77°F) for 45 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- Moderna COVID-19 Vaccine, Bivalent is a white to off-white suspension. It may contain white or translucent product-related particulates. Do not administer if vaccine is discolored or contains other particulate matter.
- A booster dose for individuals 18 years of age and older is 0.5 mL.
- Each multiple-dose vial contains 5 booster doses of 0.5 mL.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- After the first 0.5 mL booster dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine, Bivalent vial label. Discard vial after 12 hours. Do not refreeze.

2.2 Administration

Administer Moderna COVID-19 Vaccine, Bivalent intramuscularly.

2.3 Dosing and Schedule

A single booster dose (0.5 mL) of Moderna COVID-19 Vaccine, Bivalent may be administered at least 2 months after completion of primary vaccination or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine, Bivalent is a suspension for injection. Each booster dose of

Moderna COVID-19 Vaccine, Bivalent supplied in a multiple-dose vial with a dark blue cap and a label with a gray border for individuals 18 years and older is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer Moderna COVID-19 Vaccine, Bivalent to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of Moderna COVID-19 Vaccine, Bivalent [see *Description (13)*].

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Moderna COVID-19 Vaccine, Bivalent.

Monitor Moderna COVID-19 Vaccine, Bivalent recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

5.2 Myocarditis and Pericarditis

Postmarketing safety data with Moderna COVID-19 Vaccine are relevant to Moderna COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Moderna COVID-19 Vaccine, the observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

Some, but not all, observational analyses of postmarketing data suggest that there may be an increased risk of myocarditis and pericarditis in males under 40 years of age following the second dose of Moderna COVID-19 Vaccine primary series relative to other authorized or approved mRNA COVID-19 vaccines.

The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to Moderna COVID-19 Vaccine, Bivalent.

5.5 Limitations of Vaccine Effectiveness

Moderna COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of myocarditis, cases of pericarditis, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with Moderna COVID-19 Vaccine, Bivalent. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

The safety of a booster dose of Moderna COVID-19 Vaccine, Bivalent is based on:

- safety data from a clinical study which evaluated a booster dose of Moderna's bivalent COVID-19 vaccine (Original and Omicron BA.1), not authorized or approved in the U.S., hereafter referred to as bivalent vaccine (Original and Omicron BA.1),
- safety data from clinical trials which evaluated primary and booster vaccination with Moderna COVID-19 Vaccine,³ and
- postmarketing safety data with Moderna COVID-19 Vaccine

The safety data accrued with the bivalent vaccine (Original and Omicron BA.1) and with Moderna COVID-19 Vaccine are relevant to Moderna COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process. The bivalent vaccine (Original and Omicron BA.1) contained 25 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized S-glycoprotein of SARS-CoV-2 Wuhan-Hu-1 strain (Original) and 25 mcg of mRNA encoding the S-glycoprotein of SARS-CoV-2 Omicron variant lineage BA.1, for a total of 50 mcg mRNA per dose. This is the same total quantity of mRNA per dose as a dose of Moderna COVID-19 Vaccine, Bivalent and as a booster dose of Moderna COVID-19 Vaccine (previously authorized for booster vaccination in individuals 18 years of age and older), and half

³ Moderna COVID-19 Vaccine is a monovalent vaccine that encodes the spike protein of only the Original SARS-CoV-2.

the total quantity of mRNA as a primary series dose of Moderna COVID-19 Vaccine for individuals 12 years of age and older.

In a clinical study, the adverse reactions in participants 18 years of age and older following administration of a booster dose of bivalent vaccine (Original and Omicron BA.1) included pain at the injection site (77.3%), fatigue (54.9%), headache (43.9%), myalgia (39.6%), arthralgia (31.1%), chills (23.8%), axillary swelling/tenderness (17.4%), nausea/vomiting (10.3%), erythema at the injection site (6.9%), swelling at the injection site (6.9%), and fever (4.4%).

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of Moderna COVID-19 Vaccine outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

In five clinical trials (NCT04283461, NCT04405076, NCT04470427, NCT04649151, NCT04796896), approximately 40,000 participants aged 6 months and older received at least one dose of Moderna COVID-19 Vaccine. In one clinical trial (NCT04927065), approximately 400 participants 18 years of age and older received one dose of bivalent vaccine (Original and Omicron BA.1).

Study 1 (NCT04470427) is a Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,346 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine⁴ (n=15,184) or placebo (n=15,162). Study 2 (NCT04405076) is a Phase 2, randomized, observer-blind, placebo-controlled, dose-confirmation study, which included an open-label phase involving 171 participants 18 years of age and older who received a booster dose of Moderna COVID-19 Vaccine 6 months (range of 5.8 to 8.5 months) after receiving the second dose of the primary series. Study 3 (NCT04649151) is a Phase 2/3 randomized, placebo-controlled, observer-blind, clinical trial conducted in the United States involving 3,726 participants 12 years through 17 years of age who received at least one dose of Moderna COVID-19 Vaccine (n=2,486) or placebo (n=1,240). Study 4 (NCT04796896) includes an ongoing Phase 2/3 randomized, placebo-controlled, observer-blind clinical trial component conducted in the United States and Canada involving 10,390 participants 6 months through 11 years of age who received at least one dose of Moderna COVID-19 Vaccine (n=7,799) or placebo (n=2,591). Study 5 (NCT04927065) is Phase 2/3 open-label study in which 437 participants 18 years of age and older, who had received a two dose primary series and one booster dose of Moderna COVID-19 Vaccine, received a second booster dose with the bivalent vaccine (Original and Omicron BA.1) at least 3 months after the first booster dose.

⁴ Moderna COVID-19 Vaccine is marketed as SPIKEVAX (COVID-19 Vaccine, mRNA), which is approved for use in individuals 18 years of age and older.

Bivalent Vaccine (Original and Omicron BA.1) Administered as a Second Booster Dose

Study 5 (NCT04927065), a Phase 2/3 open-label study conducted in the United States, evaluated the immunogenicity, safety, and reactogenicity of a booster dose of the bivalent vaccine (Original and Omicron BA.1) compared to a booster dose of Moderna COVID-19 Vaccine when administered as a second booster dose to participants 18 years of age and older who had previously received a primary series and a first booster dose with Moderna COVID-19 Vaccine at least 3 months prior. The safety analysis set included 437 participants in the bivalent vaccine (Original and Omicron BA.1) booster dose group and 377 participants in the Moderna COVID-19 Vaccine booster dose group.

The median age of the population was 60 years (range 20-96); 490 (60.2%) participants were 18 through 64 years of age and 324 (39.8%) were 65 years and older. Overall, 44.8% were male, 55.2% were female, 10.2% were Hispanic or Latino, 86.4% were White, 7.4% were African American, 3.7% were Asian, 0.1% were American Indian or Alaska Native, 0.1% were Native Hawaiian or Pacific Islander, 0.6% were other races, and 1.1% were Multiracial. Demographic characteristics were similar among participants who received the bivalent vaccine (Original and Omicron BA.1) and those who received Moderna COVID-19 Vaccine. Following the booster dose through the cutoff date of April 27, 2022, the median follow-up time was 43 days among bivalent vaccine (Original and Omicron BA.1) recipients and 57 days among Moderna COVID-19 Vaccine recipients.

Solicited Adverse Reactions

Local and systemic adverse reactions and use of antipyretic medication were solicited in an electronic diary for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving bivalent vaccine (Original and Omicron BA.1) and participants receiving Moderna COVID-19 Vaccine. Events that persisted for more than 7 days were followed until resolution.

Table 1 and Table 2 present the frequency and severity of reported solicited local and systemic adverse reactions within 7 days following a second booster dose with bivalent vaccine (Original and Omicron BA.1) booster dose compared to Moderna COVID-19 Vaccine in participants 18 to <65 years of age and ≥ 65 years of age.

Table 1: Number and Percentage of Participants 18 Years Through 64 Years of Age With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days After a Second Booster Dose with Bivalent Vaccine (Original and BA.1) Compared to a Second Booster Dose with Moderna COVID-19 Vaccine (Solicited Safety Set)*

	Bivalent Vaccine (Original and Omicron BA.1) Booster Dose (N=263) n (%)	Moderna COVID-19 Vaccine Booster Dose (N=211) n (%)
Local Adverse Reactions		
Pain	231 (87.8)	175 (82.9)
Pain, Grade 3 ^a	2 (0.8)	4 (1.9)
Axillary swelling/tenderness	56 (21.3)	39 (18.5)
Axillary swelling/tenderness, Grade 3 ^a	0 (0)	4 (1.9)
Swelling (hardness) ≥25 mm	22 (8.4)	15 (7.1)
Swelling (hardness), Grade 3 ^b	4 (1.5)	2 (0.9)
Erythema (redness) ≥25 mm	20 (7.6)	10 (4.7)
Erythema (redness), Grade 3 ^b	7 (2.7)	1 (0.5)
Systemic Adverse Reactions		
Fatigue	154 (58.6)	115 (54.5)
Fatigue, Grade 3 ^c	10 (3.8)	7 (3.3)
Headache	129 (49.0)	100 (47.4)
Headache, Grade 3 ^d	4 (1.5)	1 (0.5)
Myalgia	113 (43.0)	90 (42.7)
Myalgia, Grade 3 ^c	9 (3.4)	8 (3.8)
Arthralgia	87 (33.1)	69 (32.7)
Arthralgia, Grade 3 ^c	3 (1.1)	2 (0.9)
Chills	64 (24.3)	54 (25.6)
Chills, Grade 3 ^e	1 (0.4)	0 (0)
Nausea/vomiting	35 (13.3)	27 (12.8)
Fever	10 (3.8)	10 (4.7)
Fever, Grade 3 ^f	1 (0.4)	0 (0)
Use of antipyretic or pain medication	104 (39.5)	67 (31.8)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary). Solicited Safety Set consisted of participants who received a booster dose and contributed solicited adverse reaction data. Absence of rows for Grade 3 or Grade 4 adverse reactions indicates no events were reported.

^a Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

^b Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

^c Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

^d Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

^e Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

^f Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.

Table 2: Number and Percentage of Participants ≥65 Years of Age With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days After a Second Booster Dose with Bivalent Vaccine (Original and Omicron BA.1) Compared to a Second Booster Dose with Moderna COVID-19 Vaccine (Solicited Safety Set)*

	Bivalent Vaccine (Original and Omicron BA.1) Booster Dose (N=174) n (%)	Moderna COVID-19 Vaccine Booster Dose (N=140) n (%)
Local Adverse Reactions		
Pain	107 (61.5)	94 (67.1)
Pain, Grade 3 ^a	2 (1.1)	0 (0)
Axillary swelling/tenderness	20 (11.5)	15 (10.7)
Axillary swelling/tenderness, Grade 3 ^a	1 (0.6)	0 (0)
Swelling (hardness) ≥25 mm	8 (4.6)	8 (5.7)
Swelling (hardness), Grade 3 ^b	1 (0.6)	3 (2.1)
Erythema (redness) ≥25 mm	10 (5.7)	3 (2.1)
Erythema (redness), Grade 3 ^b	2 (1.1)	1 (0.7)
Systemic Adverse Reactions		
Fatigue	86 (49.4)	65 (46.8)
Fatigue, Grade 3 ^c	5 (2.9)	4 (2.9)
Myalgia	60 (34.5)	45 (32.4)
Myalgia, Grade 3 ^c	1 (0.6)	5 (3.6)
Headache	63 (36.2)	44 (31.7)
Headache, Grade 3 ^d	1 (0.6)	1 (0.7)
Arthralgia	49 (28.2)	42 (30.2)
Arthralgia, Grade 3 ^c	1 (0.6)	1 (0.7)
Chills	40 (23.0)	20 (14.4)
Chills, Grade 3 ^e	0 (0)	1 (0.7)
Nausea/vomiting	10 (5.7)	8 (5.8)
Nausea/vomiting, Grade 3 ^f	1 (0.6)	0 (0)
Fever	9 (5.2)	2 (1.4)
Use of antipyretic or pain medication	46 (26.4)	40 (28.6)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary). Solicited Safety Set consisted of participants who received a booster dose and contributed solicited adverse reaction data. Absence of rows for Grade 3 or Grade 4 adverse reactions indicates no events were reported.

^a Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

^b Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

^c Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

^d Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

^e Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

^f Grade 3 nausea/vomiting: Defined as prevents daily activity; requires outpatient intravenous hydration.

The median duration of solicited local and systemic adverse reactions was 2 days in participants who received either vaccine booster dose.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following the booster dose. Serious adverse events and medically attended adverse events will be recorded for the entire study duration. As of April 27, 2022, among participants who had received a booster dose (bivalent vaccine [Original and Omicron BA.1]=437, Moderna COVID-19 Vaccine=377), unsolicited adverse events that occurred within 28 days following vaccination were reported by 18.5% of participants (n=81) who received bivalent vaccine (Original and Omicron BA.1) and 20.7% of participants (n=78) who received Moderna COVID-19 Vaccine. In these analyses, 99.9% of study participants had at least 28 days of follow-up after the booster dose. The incidence of unsolicited adverse events was similar between the vaccine groups and no new safety concerns were identified.

Serious Adverse Events

As of April 27, 2022, the median duration of follow-up was 43 days among bivalent vaccine (Original and Omicron BA.1) recipients and 57 days among Moderna COVID-19 Vaccine recipients. Serious adverse events were reported by 0.7% (n=3) of participants who received bivalent vaccine (Original and Omicron BA.1) and 0.3% (n=1) of participants who received Moderna COVID-19 Vaccine. None of the events in the bivalent vaccine (Original and Omicron BA.1) group or Moderna COVID-19 Vaccine group were considered related to vaccine.

Moderna COVID-19 Vaccine Administered as a Two-Dose Primary Series

Participants 18 Years and Older

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,346 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,184) or placebo (n=15,162) (Study 1, NCT04470427). Upon issuance of the Emergency Use Authorization (December 18, 2020) for Moderna COVID-19 Vaccine, participants were unblinded in a phased manner over a period of months to offer placebo participants Moderna COVID-19 Vaccine. The median duration of follow up for safety after the second injection during the blinded phase was 4 months. The median duration of follow up for safety after the second injection including both the blinded phase and the open-label phase was 6 months.

In Study 1, the median age of the population was 52 years (range 18-95); 22,826 (75.2%) participants were 18 to 64 years of age and 7,520 (24.8%) participants were 65 years of age and older. Overall, 52.6% of the participants were male, 47.4% were female, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.0% were other races, and 2.1% were Multiracial. Demographic characteristics were similar between participants who received Moderna COVID-19 Vaccine and those who received placebo.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for 28 days following each dose. Serious adverse events and medically attended adverse events will be recorded for the entire study duration (2 years). Among the 30,346 participants who had received at least 1 dose of vaccine (N=15,184) or placebo (N=15,162), unsolicited adverse events that occurred within 28 days following any vaccination were reported by 31.3% of participants (n=4,752) who received Moderna COVID-19 Vaccine and 28.6% of participants (n=4,338) who received placebo.

During the 28-day follow-up period following any dose, lymphadenopathy-related events were reported by 1.7% of vaccine recipients and 0.8% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass.

During the 7-day follow-up period of any vaccination, hypersensitivity events of injection site rash or injection site urticaria, likely related to vaccination, were reported by 6 participants in the Moderna COVID-19 Vaccine group and none in the placebo group. Delayed injection site reactions that began >7 days after vaccination were reported in 1.4% of vaccine recipients and 0.7% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

In the blinded portion of the study, there were 8 reports of facial paralysis (including Bell's palsy) in the Moderna COVID-19 Vaccine group, and 3 in the placebo group. In the 28-day follow-up period there were two cases of facial paralysis in the Moderna COVID-19 Vaccine group, which occurred on 8 and 22 days, respectively, after vaccination, and one in the placebo group, which occurred 17 days after vaccination. Currently available information on facial paralysis is insufficient to determine a causal relationship with the vaccine.

In the blinded portion of the study, there were 50 reports of herpes zoster in the Moderna COVID-19 Vaccine group, and 23 in the placebo group. In the 28-day period after any vaccination, there were 22 cases of herpes zoster in the Moderna COVID-19 Vaccine group, and 15 in the placebo group. Currently available information on herpes zoster infection is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

During the blinded phase of the study, serious adverse events were reported by 1.8% (n=268) of participants who received Moderna COVID-19 Vaccine and 1.9% (n=292) of participants who received placebo.

There were three serious adverse events of angioedema/ facial swelling in the vaccine group in recipients with a history of injection of dermatological fillers. The onset of swelling was reported

1-2 days after the second dose and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Adolescents 12 Years Through 17 Years of Age

Safety data for Moderna COVID-19 Vaccine in adolescents were collected in an ongoing Phase 2/3 randomized, placebo-controlled, observer-blind, clinical trial conducted in the United States involving 3,726 participants 12 years through 17 years of age who received at least one dose of Moderna COVID-19 Vaccine (n=2,486) or placebo (n=1,240) (Study 3, NCT04649151).

Overall, 51.4% were male, 48.6% were female, 11.6% were Hispanic or Latino, 83.9% were White, 3.4% were African American, 5.9% were Asian, 0.5% were American Indian or Alaska Native, <0.1% were Native Hawaiian or Pacific Islander, 1.0% were other races, and 4.5% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose. Serious adverse events and medically attended adverse events will be recorded for the entire study duration. As of May 8, 2021, among participants who had received at least 1 dose of vaccine or placebo (vaccine=2,486, placebo=1,240), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 20.5% of participants (n=510) who received Moderna COVID-19 Vaccine and 15.9% of participants (n=197) who received placebo. In these analyses, 97.3% of study participants had at least 28 days of follow-up after Dose 2.

A 14-year-old male experienced probable myocarditis with onset of symptoms 1 day after Dose 2 of Moderna COVID-19 Vaccine. Symptoms resolved after 8 days and no sequelae were observed at 5 months. There were no cases of myocarditis among placebo recipients.

During the 28-day follow-up period following any dose, lymphadenopathy-related events that were not necessarily captured in the 7-day e-diary were reported by 5.0% of vaccine recipients and 0.5% of placebo recipients. These events included lymphadenopathy, vaccination-site lymphadenopathy and injection-site lymphadenopathy which were plausibly related to vaccination.

During the 28-day follow-up period following any dose, hypersensitivity adverse events were reported in 1.8% of vaccine recipients and 0.6% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 0.9% of vaccine recipients and in no placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

There were no other notable patterns or numerical imbalances between treatment groups for

specific categories of adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of May 8, 2021, serious adverse events were reported by 0.2% (n=6) of participants who received Moderna COVID-19 Vaccine and 0.2% (n=2) of participants who received placebo. In these analyses, 97.3% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 53 days after Dose 2.

There were no notable patterns or imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Additional Safety Analyses

Study 3 participants started to enter an open-label, observational phase after May 10, 2021. A long-term safety analysis was conducted in participants from Study 3 who received Moderna COVID-19 Vaccine (n=2,486) with a cut-off date of January 31, 2022. In these analyses, the median duration of follow-up including both the blinded and open-label phases was 312 days after Dose 2 and 95.6% of study participants have had at least 6 months of follow-up after Dose 2. Through the cut-off date, there were no serious adverse events causally related to the vaccine.

Individuals 6 Years Through 11 Years of Age

Safety data for Moderna COVID-19 Vaccine from Study 4 included data in 4,002 participants 6 years through 11 years of age who received at least one dose of Moderna COVID-19 Vaccine (n=3,007) or placebo (n=995). As of the data cutoff date of November 10, 2021, the median duration of blinded follow-up for safety was 51 days after Dose 2, and 1,284 participants had been followed for at least 2 months after Dose 2 (vaccine=1,006, placebo=218).

Demographic characteristics in Study 4 were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo. Overall, 50.8% were male, 49.2% were female, 18.5% were Hispanic or Latino, 65.6% were White, 10.0% were African American, 9.9% were Asian, 0.4% were American Indian or Alaska Native, <0.1% were Native Hawaiian or Pacific Islander, 2.1% were other races, and 10.6% were Multiracial.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose. Serious adverse events and medically attended adverse events will be recorded for the entire study duration. As of November 10, 2021, among participants who had received at least 1 dose of vaccine or placebo (vaccine=3,007, placebo=995), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 29.6% of participants (n=891) who received Moderna COVID-19 Vaccine and 25.1% of participants (n=250) who received placebo. In these analyses, 98.6% of study participants had at least 28 days of follow-up after Dose 2.

During the 28-day follow-up period following any dose, lymphadenopathy-related events were reported by 1.8% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymph node pain, injection-site lymphadenopathy, and vaccination-site lymphadenopathy which were plausibly related to vaccination.

During the 28-day follow-up period following any dose, hypersensitivity adverse events were reported in 4.3% of vaccine recipients and 2.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 2.7% of vaccine recipients and in 0.2% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

During the 28-day follow-up period following any dose, events of abdominal pain (including abdominal pain, abdominal pain upper, and abdominal pain lower) were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. Currently available information is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of November 10, 2021, serious adverse events were reported by 0.2% (n=6) of participants who received Moderna COVID-19 Vaccine and 0.2% (n=2) participants who received placebo. None of the events in the Moderna COVID-19 Vaccine group were considered related to vaccine. In these analyses, 98.6% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 51 days after Dose 2.

There were no notable patterns or imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Additional Safety Analyses

Participants 6 years through 11 years in Study 4 started to enter an open-label, observational phase after November 1, 2021. A long-term safety analysis was conducted in participants 6 years through 11 years from Study 4 who received Moderna COVID-19 Vaccine (n=3,007) with a cut-off date of February 21, 2022. In these analyses, the median duration of follow-up including both the blinded and open-label phases was 158 days after Dose 2. Through the cut-off date, there were no serious adverse events causally related to the vaccine.

Individuals 6 Months Through 5 Years of Age

Safety data for Moderna COVID-19 Vaccine from Study 4 included data in 6,388 participants 6 months through 5 years of age who received at least one dose of Moderna COVID-19 Vaccine

(n=4,792) or placebo (n=1,596). As of the data cutoff date of February 21, 2022, the median duration of blinded follow-up for safety for participants 6 months through 23 months was 68 days after Dose 2. For participants 2 years to 5 years, the median duration of blinded follow-up for safety was 71 days after Dose 2.

For participants 6 months through 23 months, 51.1% were male, 48.9% were female, 13.2% were Hispanic or Latino, 79.0% were White, 3.1% were African American, 4.9% were Asian, 0.2% were American Indian or Alaska Native, 0.0% were Native Hawaiian or Pacific Islander, 1.5% were other races, and 10.6% were Multiracial. For participants 2 years through 5 years, 50.8% were male, 49.2% were female, 14.2% were Hispanic or Latino, 76.5% were White, 4.5% were African American, 6.0% were Asian, 0.4% were American Indian or Alaska Native, 0.3% were Native Hawaiian or Pacific Islander, 1.5% were other races, and 10.4% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration.

As of February 21, 2022, among participants 6 months through 23 months of age who had received at least 1 dose of vaccine or placebo (vaccine=1,761, placebo=589), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 49.3% of participants (n=869) who received Moderna COVID-19 Vaccine and 48.2% of participants (n=284) who received placebo. In these analyses, 83.1% of study participants 6 months through 23 months of age had at least 28 days of follow-up after Dose 2. Among participants 2 years through 5 years of age who had received at least 1 dose of vaccine or placebo (vaccine=3,031, placebo=1,007), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 40.0% of participants (n=1,212) who received Moderna COVID-19 Vaccine and 37.5% of participants (n=378) who received placebo. In these analyses, 89.3% of study participants 2 years through 5 years of age had at least 28 days of follow-up after Dose 2.

During the 28-day follow-up period following any dose, lymphadenopathy-related events were reported by 1.5% of vaccine recipients and 0.2% of placebo recipients who were 6 months through 23 months of age and 0.9% of vaccine recipients and <0.1% of placebo recipients who were 2 years through 5 years of age. These events included lymphadenopathy, injection-site lymphadenopathy, and vaccination-site lymphadenopathy which were plausibly related to vaccination.

During the 28-day follow-up period following any dose, hypersensitivity adverse events were reported in 3.9% of vaccine recipients and 5.3% of placebo recipients who were 6 months through 23 months of age and 3.5% of vaccine recipients and 2.5% of placebo recipients who were 2 years through 5 years of age. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 1.2% of vaccine

recipients and no placebo recipients who were 6 months through 23 months of age and 1.4% of vaccine recipients and <0.1% of placebo recipients who were 2 years through 5 years of age. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

During the 28-day follow-up period following any dose, events of abdominal pain (including abdominal pain, abdominal pain upper, and abdominal discomfort) were reported by 0.7% of vaccine recipients and 0.4% of placebo recipients who were 2 years through 5 years of age. Currently available information is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of February 21, 2022, serious adverse events were reported by 0.9% (n=15) of participants who received vaccine and 0.2% (n=1) of participants who received placebo who were 6 months through 23 months of age and 0.3% (n=9) of participants who received Moderna COVID-19 Vaccine and 0.2% (n=2) of participants who received placebo who were 2 years through 5 years of age. In these analyses, 83.1% of study participants 6 months through 23 months of age had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 68 days after Dose 2. In these analyses, 89.3% of study participants 2 years through 5 years of age had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 71 days after Dose 2.

In participants 6 months through 23 months of age who received the vaccine, a 1-year-old female experienced serious adverse events of a Grade 3 fever 6 hours after Dose 1 and a febrile convulsion 1 day after Dose 1. These events were considered related to vaccination. In participants 2 years through 5 years of age who received Moderna COVID-19 Vaccine, none of the events were considered related to vaccine.

Moderna COVID-19 Vaccine Administered as a First Booster Dose Following a Primary Series of Moderna COVID-19 Vaccine in Participants 18 Years and Older

Study 2 is a Phase 2, randomized, observer-blind, placebo-controlled, dose-confirmation study to evaluate the safety, reactogenicity, and immunogenicity of Moderna COVID-19 Vaccine in participants 18 years of age and older (NCT04405076). In this study, 198 participants received two doses (0.5 mL 1 month apart) of Moderna COVID-19 Vaccine primary series. In an open label-phase, 171 of those participants received a single booster dose (0.25 mL) at least 6 months (range of 5.8 to 8.5 months) after receiving the second dose of the primary series.

Among the 171 booster dose recipients, the median age was 55 years (range 18-87), 39.2% were male and 60.8% were female, 95.9% were White, 5.8% were Hispanic or Latino, 2.9% were Black or African American, 0.6% were Asian, and 0.6% were American Indian or Alaska

Native. Following the booster dose, the median follow-up time was 5.7 months (range of 3.1 to 6.4 months).

Solicited Adverse Reactions

Table 3 presents the frequency and severity of reported solicited local and systemic adverse reactions among Study 2 Moderna COVID-19 Vaccine booster dose recipients 18 to <65 years of age and ≥65 years of age within 7 days of a booster vaccination.

Table 3: Number and Percentage of Participants 18 Years of Age and Older With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After the Moderna COVID-19 Vaccine Booster Dose (Solicited Safety Set)†

	Participants 18 Years Through 64 Years (N=129) n (%)	Participants ≥65 Years (N=38) n (%)
Local Adverse Reactions		
Pain	111 (86.0)	29 (76.3)
Pain, Grade 3 ^a	4 (3.1)	2 (5.3)
Axillary swelling/tenderness	32 (24.8)	2 (5.3)
Axillary swelling/tenderness, Grade 3 ^a	1 (0.8)	0 (0)
Swelling (hardness) ≥25 mm	8 (6.2)	1 (2.6)
Swelling (hardness), Grade 3 ^b	0 (0)	1 (2.6)
Erythema (redness) ≥25 mm	7 (5.4)	1 (2.6)
Erythema (redness), Grade 3 ^b	1 (0.8)	0 (0.0)
Systemic Adverse Reactions		
Fatigue	80 (62.0)	18 (47.4)
Fatigue, Grade 3 ^c	4 (3.1)	3 (7.9)
Headache	76 (58.9)	16 (42.1)
Headache, Grade 3 ^d	1 (0.8)	1 (2.6)
Myalgia	64 (49.6)	18 (47.4)
Myalgia, Grade 3 ^c	4 (3.1)	1 (2.6)
Arthralgia	54 (41.9)	15 (39.5)
Arthralgia, Grade 3 ^c	4 (3.1)	1 (2.6)
Chills	52 (40.3)	7 (18.4)
Nausea/vomiting	16 (12.4)	3 (7.9)
Fever	9 (7.0)	2 (5.4)
Fever, Grade 3 ^e	2 (1.6)	0 (0.0)
Rash	3 (2.3)	0 (0)
Use of antipyretic or pain medication	64 (49.6)	11 (28.9)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

† Absence of rows for Grade 3 or Grade 4 adverse reactions indicates no events were reported.

^a Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

^b Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

^c Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

^d Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

^e Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.

Revised: Aug/31/2022

In participants who received a booster dose, the median duration of solicited local and systemic adverse reactions was 2 to 3 days.

Unsolicited Adverse Events

Overall, the 171 participants who received a booster dose had a median follow-up time of 5.7 months after the booster dose to the cut-off date (August 16, 2021). Through the cut-off date, there were no unsolicited adverse events not already captured as solicited local and systemic reactions that were considered causally related to Moderna COVID-19 Vaccine.

Serious Adverse Events

Of the 171 participants who received a booster dose of Moderna COVID-19 Vaccine, there were no serious adverse events reported from the booster dose through 28 days after the booster dose. Through the cut-off date of August 16, 2021, there were no serious adverse events following the booster dose considered causally related to Moderna COVID-19 Vaccine.

Moderna COVID-19 Vaccine Administered as a First Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine

The safety of a Moderna COVID-19 Vaccine booster dose in individuals who completed primary vaccination with another authorized or approved COVID-19 vaccine (heterologous booster dose) is inferred from the safety of a Moderna COVID-19 Vaccine booster dose administered following completion of a Moderna COVID-19 Vaccine primary series (homologous booster dose) and from data from an independent Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a booster dose of Moderna COVID-19 Vaccine. The booster dose that study participants received contained twice the amount of mRNA compared to the authorized booster dose of Moderna COVID-19 Vaccine. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks (range 12 to 20 weeks) prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Adverse events were assessed through 28 days after the booster dose. An overall review of adverse reactions reported following the Moderna COVID-19 Vaccine heterologous booster dose did not identify any new safety concerns, as compared with adverse reactions reported following Moderna COVID-19 Vaccine primary series doses or homologous booster dose.

Moderna COVID-19 Vaccine Administered as a Second Booster Dose Following Primary and Booster Vaccination with Another Authorized or Approved COVID-19 Vaccine

In an independently conducted study (*Gili Regev-Yochay, Tal Gonen, Mayan Gilboa, et al. 2022 DOI: 10.1056/NEJMc2202542*), Moderna COVID-19 Vaccine was administered as a second booster dose to 120 participants 18 years of age and older who had received a 2-dose primary

series and a first booster dose of Pfizer-BioNTech COVID-19 Vaccine at least 4 months prior. No new safety concerns were reported during up to three weeks of follow-up after the second booster dose.

6.2 Post-Authorization Experience

The following adverse reactions have been identified during post-authorization use of Moderna COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis

Immune System Disorders: anaphylaxis

Nervous System Disorders: syncope

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following administration of the Moderna COVID-19 Vaccine, Bivalent to the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of myocarditis
- Cases of pericarditis
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: <https://vaers.hhs.gov/reportevent.html>, or

- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine, Bivalent
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine, Bivalent and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
 - a. Write “Moderna COVID-19 Vaccine, Bivalent EUA” as the first line
 - b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
 - a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
 - b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
 - c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider’s office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of Moderna COVID-19 Vaccine, Bivalent with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine, Bivalent during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine, Bivalent during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Data are not available on Moderna COVID-19 Vaccine, Bivalent administered to pregnant women.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single primary series dose of Moderna COVID-19 Vaccine for individuals 12 years of age and older was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Moderna COVID-19 Vaccine, Bivalent on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Moderna COVID-19 Vaccine, Bivalent is not authorized for use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Moderna COVID-19 Vaccine and the bivalent vaccine (Original and Omicron BA.1) included participants 65 years of age and older, and their data contribute to the overall assessment of safety and effectiveness of Moderna COVID-19 Vaccine, Bivalent. *[see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)]*. Some local and systemic adverse reactions were reported in a lower proportion of participants 65 years of age and older compared to participants 18 through 64 years of age *[see Overall Safety Summary (6.1)]*.

In an ongoing Phase 3 clinical study (Study 1) of primary series dosing of Moderna COVID-19 Vaccine, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older.

In an ongoing Phase 2/3 clinical study (Study 5) of a single booster dose of bivalent vaccine (Original and BA.1), 39.8% (n=174) were 65 years of age and older

In a Phase 2 clinical study (Study 2) of a single booster dose of Moderna COVID-19 Vaccine, 22.2% (n=38) of participants were 65 years of age and older.

13 DESCRIPTION

Moderna COVID-19 Vaccine, Bivalent is provided as a sterile white to off-white suspension for intramuscular injection.

Each 0.5 mL booster dose of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) contains 25 mcg nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of the SARS-CoV-2 Wuhan-Hu-1 strain (Original) and 25 mcg mRNA encoding the pre-fusion stabilized S-protein of the SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 (Omicron BA.4/BA.5). The S-proteins of the SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 are identical. Each dose also contains the following ingredients: a total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine, Bivalent does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in Moderna COVID-19 Vaccine, Bivalent is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

The effectiveness of a booster dose of Moderna COVID-19 Vaccine, Bivalent is based on effectiveness of primary and booster vaccination with Moderna COVID-19 Vaccine and immunogenicity of a second booster dose with the bivalent vaccine (Original and Omicron BA.1).

18.1 Efficacy of Two-Dose Primary Series of Moderna COVID-19 Vaccine in Participants 18 Years and Older

Study 1 is an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set) included 28,207 participants who received two doses (0.5 mL at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073) and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were White, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per-Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

Efficacy Against COVID-19

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever ($\geq 38^{\circ}\text{C}$ / $\geq 100.4^{\circ}\text{F}$), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow-up for efficacy for participants in the study was 9 weeks post-Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 4: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI) [†]
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.

[†] VE and 95% CI from the stratified Cox proportional hazard model.

The subgroup analyses of vaccine efficacy are presented in Table 5.

Table 5: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.

† VE and 95% CI from the stratified Cox proportional hazard model.

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥ 30 per minute, heart rate ≥ 125 beats per minute, SpO2 $\leq 93\%$ on room air at sea level or PaO2/FIO2 < 300 mm Hg; or respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure < 90 mmHg, diastolic BP < 60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

18.2 Immunogenicity of the Bivalent Vaccine (Original and Omicron BA.1) Administered as a Second Booster Dose

Study 5 is a Phase 2/3 open-label study in which participants 18 years of age and older, who had previously received a two-dose primary series and one booster dose of Moderna COVID-19 Vaccine, received a second booster dose with the bivalent vaccine (Original and Omicron BA.1) at least 3 months after the first booster dose. The primary immunogenicity analysis population included 334 participants who received a booster dose of bivalent vaccine (Original and Omicron BA.1) and 260 participants who received a booster dose of Moderna COVID-19 Vaccine. Participants included in the analysis population had no serologic or virologic evidence of SARS-CoV-2 infection prior to the second booster dose.

Among participants assessed for immunogenicity, the median age of the population was 62 years (range 20-96). For the bivalent vaccine (Original and Omicron BA.1) group, 195 (58.4%) participants were age 18 to 64 and 139 (41.6%) were 65 and older; 43.4% were male, 56.6% were female, 7.2% were Hispanic or Latino, 87.1% were White, 7.2% were African American, 3.3% were Asian, 0.0% were American Indian or Alaska Native, 0.0% were Native Hawaiian or Pacific Islander, 0.6% were other races, and 1.8% were Multiracial. For the Moderna COVID-19 Vaccine group, 140 (53.8%) of participants were age 18 to 64 and 120 (46.2%) were 65 and older; 48.5% of participants were male, 51.5% were female, 8.5% were Hispanic or Latino, 90.0% were White, 4.2% were African American, 4.2% were Asian, 0.0% were American Indian or Alaska Native, 0.0% were Native Hawaiian or Pacific Islander, 0.4% were other races, and 0.0% were Multiracial. Demographic characteristics were similar among participants who received bivalent vaccine (Original and Omicron BA.1) and those who received Moderna COVID-19 Vaccine.

In Study 5, the neutralizing antibody titers (50% inhibitory dose [ID50]) against a pseudovirus expressing the original SARS-CoV-2 Spike protein (D614G) and a pseudovirus expressing the Omicron BA.1 Spike protein were evaluated. Primary immunogenicity analyses compared the ID50 GMTs and seroresponse rates (the proportion achieving a ≥ 4 -fold rise in ID50 from pre-dose 1 of the primary series) 28 days following a second booster dose with bivalent vaccine (Original and Omicron BA.1) to those following a second booster dose with Moderna COVID-19 Vaccine. Analyses of GMTs met predefined success criteria for superiority against Omicron BA.1 and noninferiority against the Original strain. The analysis of seroresponse against Omicron BA.1 met the criterion for noninferiority: Lower limit of the 2-sided 97.5% CI for the percentage difference in seroresponse rate (bivalent vaccine [Original and Omicron BA.1] minus Moderna COVID-19 Vaccine) $> -10\%$. Table 6 presents the analyses of ID50 GMTs; the primary analysis of seroresponse is not shown.

Post-hoc analyses evaluated the differences in seroresponse rates (the proportion achieving a ≥ 4 -fold rise in ID50 from pre-second booster) against both the Original strain and Omicron BA.1 (Table 7).

Table 6: Neutralizing Antibody Titers (ID50) at 28 Days After a Second Booster Dose with Bivalent Vaccine (Original and Omicron BA.1) or Moderna COVID-19 Vaccine in Participants 18 Years and Older – Per-Protocol Immunogenicity SARS-CoV-2 Negative Set*

Assay	Bivalent Vaccine (Original and Omicron BA.1) N=334 GMT ^a (95% CI)	Moderna COVID-19 Vaccine N=260 GMT ^a (95% CI)	GMT Ratio ^a (Bivalent Vaccine [Original and Omicron BA.1]/Moderna COVID-19 Vaccine) (97.5% CI)	Met Success Criteria
Omicron BA.1	2479.9 (2264.5, 2715.8)	1421.2 (1283.0, 1574.4)	1.7 (1.5, 2.0)	Lower limit of 97.5% CI >1 Criterion: Yes ^b
Original SARS-CoV-2 (D614G)	6422.3 (5990.1, 6885.7)	5286.6 (4887.1, 5718.9)	1.2 (1.1, 1.4)	Lower limit of 97.5% CI ≥0.67 Criterion: Yes ^c

* Per-Protocol Immunogenicity SARS-CoV-2 Negative Set included all subjects who received the planned dose of study vaccine per schedule, had pre-booster and Day 29 neutralizing antibody data against Omicron BA.1, had no major protocol deviations that impact key or critical data, had no history of HIV infection, and had no serologic or virologic evidence of SARS-CoV-2 infection prior to the second booster dose.

^a The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the treatment variable as fixed effect, adjusting for age group (<65, ≥65 years) and pre-booster antibody titer level (in log 10 scale). The treatment variable corresponds to each individual study arm dose. The resulted least square (LS) means, difference of LS means, and confidence intervals are back transformed to the original scale for presentation.

^b Superiority is declared if the lower limit of the 2-sided 97.5% CI for the GMT ratio is >1.

^c Non-inferiority is declared if the lower limit of the 2-sided 97.5% CI for the GMT ratio is ≥0.67.

Note: Antibody values < the lower limit of quantitation (LLOQ) are replaced by 0.5 × LLOQ. Values > the upper limit of quantitation (ULOQ) are replaced by the ULOQ if actual values are not available.

Table 7: Post-hoc Analyses of Seroresponse Rates at 28 Days After a Second Booster Dose with Bivalent Vaccine (Original and Omicron BA.1) or Moderna COVID-19 Vaccine in Participants 18 Years and Older – Per-Protocol Immunogenicity SARS-CoV-2 Negative Set*

Assay	Bivalent Vaccine (Original and Omicron BA.1) Seroresponse ^a N=334 n/N1 (%) (95% CI) ^b	Moderna COVID-19 Vaccine Seroresponse ^a N=260 n/N1 (%) (95% CI) ^b	Difference in Seroresponse Rate (Bivalent Vaccine [Original and Omicron BA.1]-Moderna COVID-19 Vaccine) % (97.5% CI) ^c
Omicron BA.1	250/334 (74.9) (69.8, 79.4)	138/260 (53.1) (46.8, 59.3)	21.6 (12.9, 30.3)
Original SARS-CoV-2 (D614G)	180/334 (53.9) (48.4, 59.3)	111/260 (42.7) (36.6, 49.0)	11.2 (2.1, 20.3)

* Per-Protocol Immunogenicity SARS-CoV-2 Negative Set included all subjects who received the planned dose of study vaccine per schedule, had pre-booster and Day 29 neutralizing antibody data against Omicron BA.1, had no major protocol deviations that impact key or critical data, had no history of HIV infection, and had no serologic or virologic evidence of SARS-CoV-2 infection prior to the second booster dose.

N1=number of participants with non-missing data at pre-booster baseline and 28 days after second booster dose.

n=number of participants who achieved seroresponse at 28 days after booster dose.

^a For post-hoc assessment of seroresponse rates, baseline was pre-second booster dose; seroresponse was defined as a change from below the LLOQ to equal or above 4 x LLOQ if participant pre-second booster dose baseline was below the LLOQ, or at least a 4-fold rise if baseline is equal to or above the LLOQ.

^b 95% CI is calculated using the Clopper-Pearson method.

^c Common risk difference and 97.5% CI is calculated using the stratified Miettinen-Nurminen method to adjust for age group (<65, ≥65 years).

18.3 Immunogenicity of Moderna COVID-19 Vaccine Administered as a First Booster Dose Following a Primary Series of Moderna COVID-19 Vaccine in Participants 18 Years and Older

Effectiveness of a booster dose of the Moderna COVID-19 Vaccine was based on assessment of neutralizing antibody titers (ID50) against a pseudovirus expressing the SARS-CoV-2 Spike protein from a USA_WA1/2020 isolate carrying the D614G mutation. Immunogenicity analyses compared the ID50 following the booster dose to the ID50 following the primary series.

In an open-label phase of Study 2, participants 18 years of age and older received a single booster dose (0.25 mL) at least 6 months after completion of the primary series (two doses of 0.5 mL 1 month apart). The primary immunogenicity analysis population included 149 booster dose participants in Study 2 (including one individual who had only received a single dose of the primary series) and a random subset of 1,055 participants from Study 1 who received two doses (0.5 mL 1 month apart) of Moderna COVID-19 Vaccine. Study 1 and 2 participants included in the analysis population had no serologic or virologic evidence of SARS-CoV-2 infection prior to the first primary series dose and prior to the booster dose, respectively. Among participants assessed for immunogenicity, 60.4% were female, 6.7% were Hispanic or Latino; 95.3% were White, 3.4% were Black or African American, 0.7% were Asian, and 0.7% were American Indian or Alaskan Native; 9.4% were obese (body mass index ≥ 30 kg/m²). The median age of Study 2 participants was 56 years of age (range 18-82) and 24.8% of participants were 65 years of age and older. Study 2 participants included in the primary immunogenicity analysis population did not have pre-existing medical conditions that would place them at risk of severe COVID-19. Study 1 participants included in the primary immunogenicity analysis population were a stratified random sample which reflected the overall primary efficacy analysis population with regards to demographics and pre-existing medical conditions with a higher percentage of those ≥ 65 years of age (33.6%), with risk factors for severe COVID-19 (39.4%), and communities of color (53.5%).

Immunogenicity analyses included an assessment of ID50 geometric mean titer (GMT) ratio and difference in seroresponse rates. The analysis of the GMT ratio of ID50 following the booster dose compared to the primary series met the immunobridging criteria for a booster response. Seroresponse for a participant was defined as achieving a ≥ 4 -fold rise in ID50 from baseline (before the booster dose in Study 2 and before the first dose of the primary series in Study 1).

The lower limit of the 2-sided 95% CI for the difference in seroresponse rates between Study 1 and Study 2 was -16.7%, which did not meet the immunobridging criterion for a booster response (lower limit of 2-sided 95% CI for the percentage difference of $\geq -10\%$). These analyses are summarized in Table 8 and Table 9.

Table 8: Neutralizing Antibody Geometric Mean Titers (ID50) Against a Pseudovirus Expressing the SARS-CoV-2 Spike Protein (USA_WA1/2020 isolate carrying the D614G mutation) at 28 Days After a Booster Dose in Study 2 vs 28 Days After Completion of the Primary Series in Study 1, Participants ≥ 18 Years of Age, Per-Protocol Immunogenicity Set*

Study 2 Booster Dose N ^a =149 GMT ^b (95% CI)	Study 1 Primary Series N ^a =1053 GMT ^b (95% CI)	GMT Ratio (Study 2/Study 1)	Met Success Criteria ^c
1802 (1548, 2099)	1027 (968, 1089)	1.8 (1.5, 2.1)	Lower limit of 95% CI ≥ 0.67 Criterion: Yes Point Estimate ≥ 1.0 Criterion: Yes

* Per-Protocol Immunogenicity Set included all subjects who had both baseline (or Study 2 Day 1 for Study 2) and post-vaccination immunogenicity samples, did not have SARS-CoV-2 infection at baseline (or Study 2 Day 1 for Study 2), did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest (Day 29 for Study 2 and Day 57 for Study 1).

^a Number of subjects with non-missing data at the corresponding timepoint.

^b Given the lack of randomization in Study 2, the statistical analysis plan pre-specified an analysis of covariance model for estimating the geometric mean titer that adjusts for differences in age groups (<65 years, ≥ 65 years).

^c Immunobridging is declared if the lower limit of the 2-sided 95% CI for the GMR is >0.67 and the point estimate of the GLSM ratio is ≥ 1.0 .

Note: Antibody values $<$ the lower limit of quantitation (LLOQ) are replaced by $0.5 \times$ LLOQ. Values $>$ the upper limit of quantitation (ULOQ) are replaced by the ULOQ if actual values are not available.

GLSM = Geometric least squares mean

GMR = Geometric mean ratio

Table 9: Seroresponse Rates Against a Pseudovirus Expressing the SARS-CoV-2 Spike Protein (USA_WA1/2020 isolate carrying the D614G mutation) at 28 Days Post-Booster Dose in Study 2 and 28 Days After Completion of the Primary Series in Study 1, Participants ≥ 18 Years of Age, Per-Protocol Immunogenicity Set*

Study 2 Booster Seroresponse ^a N ^b =149 n (%) (95% CI) ^c	Study 1 Primary Series Seroresponse ^a N ^b =1050 n (%) (95% CI) ^c	Difference in Seroresponse Rate (Study 2-Study 1) % (95% CI) ^d	Met Success Criterion ^e
131 (87.9) (81.6, 92.7)	1033 (98.4) (97.4, 99.1)	-10.5 (-16.7, -6.1)	Lower limit of 95% CI $\geq -10\%$ Criterion: No

* Per-Protocol Immunogenicity Set included all subjects who had both baseline (or Study 2 Day 1 for Study 2) and post-vaccination immunogenicity samples, did not have SARS-CoV-2 infection at baseline (or Study 2 Day 1 for Study 2), did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest (Day 29 for Study 2 and Day 57 for Study 1).

^a Seroresponse is defined as ≥ 4 -fold rise of pseudovirus neutralizing antibody titers (ID50) from baseline (pre-

booster dose in Study 2 and pre-Dose 1 in Study 1), where baseline titers < LLOQ are set to LLOQ for the analysis.
^b Number of subjects with non-missing data at both baseline and the post-baseline timepoint of interest.
^c 95% CI is calculated using the Clopper-Pearson method.
^d 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.
^e Immunobridging is declared if the lower limit of the 2-sided 95% CI for the percentage difference is > -10%.

Study 2 participants who met the ≥ 4 -fold increase in titer post-booster dose (87.9%) had a lower baseline GMT of 109 (range of individual titers 9, 4393), whereas Study 2 participants who did not meet the ≥ 4 -fold increase in titers post-booster had a higher baseline GMT of 492 (range of individual titers 162, 2239).

An additional descriptive analysis evaluated seroresponse rates using baseline neutralizing antibody titers prior to Dose 1 of the primary series. As shown in Table 10 below, the booster dose seroresponse rate, with seroresponse defined as at least a 4-fold rise relative to the pre-Dose 1 titer, was 100%. The difference in seroresponse rates in this post-hoc analysis was 1.6% (95% CI -0.9, 2.6).

Table 10: Analysis of Seroresponse Rates Against a Pseudovirus Expressing the SARS-CoV-2 Spike Protein (USA_WA1/2020 isolate carrying the D614G mutation) at 28 Days Post-Booster Dose in Study 2 and 28 Days After Completion of the Primary Series in Study 1, Participants ≥ 18 Years of Age, Per-Protocol Immunogenicity Set*

Study 2 Booster Seroresponse^a N^b=148 n (%) (95% CI)^d	Study 1 Primary Series Seroresponse^a N^c=1050 n (%) (95% CI)^d	Difference in Seroresponse Rate (After Booster-After Primary Series) % (95% CI)^e
148 (100) (97.5, 100)	1033 (98.4) (97.4, 99.1)	1.6 (-0.9, 2.6)

* Per-Protocol Immunogenicity Set included all subjects who had non-missing data at baseline (before Dose 1) and 28 days post-booster in Study 2 or 28 days post-Dose 2 in the primary series in Study 1, respectively, did not have SARS-CoV-2 infection at pre-booster in Study 2 or baseline in Study 1, did not have a major protocol deviation that impacted immune response, and had post-injection immunogenicity assessment at timepoint of primary interest.

^a Seroresponse is defined as ≥ 4 -fold rise of pseudovirus neutralizing antibody titers (ID50) from pre-Dose 1, where baseline titers < LLOQ are set to LLOQ for the analysis.
^b Number of subjects with non-missing data at baseline (before Dose 1) and 28 days post-booster in Study 2.
^c Number of subjects with non-missing data at baseline (before Dose 1) and 28 days post-Dose 2 in the primary series in Study 1.
^d 95% CI is calculated using the Clopper-Pearson method.
^e 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.

18.4 Immunogenicity of Moderna COVID-19 Vaccine Administered as a First Booster Dose Following Primary Vaccination with Another Authorized or Approved COVID-19 Vaccine

Effectiveness of a Moderna COVID-19 Vaccine booster dose in individuals who completed primary vaccination with another authorized or approved COVID-19 vaccine (heterologous booster dose) is inferred from immunogenicity data supporting effectiveness of a Moderna COVID-19 Vaccine booster dose administered following completion of a Moderna COVID-19

Vaccine primary series and from immunogenicity data from an independent Phase 1/2 open-label clinical trial (NCT04889209) conducted in the United States that evaluated a booster dose of the Moderna COVID-19 Vaccine. The booster dose that study participants received contained twice the amount of mRNA compared to the authorized booster dose of the Moderna COVID-19 Vaccine. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks (range 12 to 20 weeks) prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Neutralizing antibody titers, as measured by a pseudovirus neutralization assay using a lentivirus expressing the SARS-CoV-2 Spike protein with D614G mutation, were assessed on Day 1 prior to administration of the booster dose and on Day 15 after the booster dose. A booster response to the Moderna COVID-19 Vaccine was demonstrated regardless of the vaccine used for primary vaccination.

19 HOW SUPPLIED/STORAGE AND HANDLING

The information in this section applies to Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) that is supplied in multiple-dose vials with dark blue caps and labels with a gray border. These multiple-dose vials are supplied as follows:

NDC 80777-282-99 Carton of 10 multiple-dose vials, each containing 2.5 mL

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Frozen Storage

Store frozen between -50°C to -15°C (-58°F to 5°F).

Storage after Thawing

- Storage at 2°C to 8°C (36°F to 46°F):
 - Vials may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.
 - Vials should be discarded 12 hours after the first puncture.
- Storage at 8°C to 25°C (46°F to 77°F):
 - Vials may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours.
 - Vials should be discarded 12 hours after the first puncture.
 - Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.

Do not refreeze once thawed.

Thawed vials can be handled in room light conditions.

Transportation of Thawed Vials at 2°C to 8°C (36°F to 46°F)

If transport at -50°C to -15°C (-58°F to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2°C to 8°C (36°F to 46°F) when shipped using shipping containers which have been qualified to maintain 2°C to 8°C (36°F to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2°C to 8°C (36°F to 46°F), vials should not be refrozen and should be stored at 2°C to 8°C (36°F to 46°F) until use.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the “VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS.”

The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at:

<https://www.cdc.gov/vaccines/programs/iis/about.html>.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

Email	Telephone number
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

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Patent(s): www.modernatx.com/patents

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