Product Monograph

Including Patient Medication Information

mRESVIA®

Respiratory Syncytial Virus (RSV) mRNA Vaccine

Dispersion for intramuscular injection

Single-dose pre-filled syringe, 50 mcg/0.5 mL

Active Immunizing Agent

ATC Code: J07BX05

Moderna Biopharma Canada Corporation Name

155 Wellington St. W, Suite 3130
Toronto, ON
M5V 3H1

Date of Authorization:

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Control Number: 294768

Recent Major Label Changes

1. Indications	2026-01
4. Dosage and administration, 4.4 administration	2026-01

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1. Indications

- adults 60 years of age and older
- adults 18 through 59 years of age who are at increased risk for LRTD caused by RSV (see Clinical Trials).

The National Advisory Committee on Immunization (NACI) provides additional guidance on the use of RSV vaccines in Canada. Please refer to the Respiratory syncytial virus (RSV) vaccines: Canadian Immunization Guide and current vaccine statements.

1.1. Pediatrics

The safety and efficacy of mRESVIA in individuals under 18 years of age have not been assessed in clinical trials.

1.2. Geriatrics

Clinical studies include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy of mRESVIA (see 8 Adverse Reactions and 14 Clinical Trials).

2. Contraindications

mRESVIA is contraindicated in individuals who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 Dosage Forms, Strengths, Composition, and Packaging.

4. Dosage and Administration

4.2. Recommended Dose and Dosage Adjustment

mRESVIA is administered as a single dose of 0.5 mL intramuscularly.

4.3. Reconstitution

mRESVIA **must not** be reconstituted, mixed with other medicinal products, or diluted. No dilution is required prior to administration.

4.4. Administration

Preparation

mRESVIA is supplied as a frozen dispersion in a pre-filled syringe that does not contain preservative.

Thaw each pre-filled syringe before use, either in the refrigerator or at room temperature, following the instructions in Table 1.

Table 1 – Thawing Conditions and Times Based on Configuration and Temperature

Configuration	Thaw in Refrigerator 2°C to 8°C	Thaw at Room Temperature 15°C to 25°C
One pre-filled syringe	Thaw for 1 hour and 40 minutes	Thaw for 40 minutes
Carton of ten (10) pre-filled syringes	Thaw for 2 hours and 40 minutes	Thaw for 1 hour and 20 minutes

- After thawing, **do not refreeze**.
- Syringes **should not** be returned to the refrigerator after being thawed at room temperature.
- The pre-filled syringes may be stored at room temperature for a total of 24 hours after removal from refrigerated conditions. Discard the pre-filled syringe if not used within this time.
- **Do not shake.**

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration. mRESVIA is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discolored or contains other particulate matter.

Administration

Administer a single 0.5 mL dose of mRESVIA intramuscularly (IM). The preferred site is the deltoid muscle of the upper arm. Do not administer this product intravenously. mRESVIA should not be combined through reconstitution or mixed with any other vaccine.

- Use a sterile needle of the appropriate size for intramuscular injection.
- With tip cap upright, remove tip cap by twisting counter-clockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.
- Uncap the needle when ready for administration.
- Administer the entire dose intramuscularly.

Disposal

Discard syringe after use

5. Overdose

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

Table 2 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular injection	Dispersion, (50 mcg/0.5 mL) Each 0.5 mL dose of mRESVIA contains 50 mcg of mRNA encoding RSV glycoprotein F stabilized in the prefusion conformation, 5'(m7G-5'-ppp-5'-Gm) cap, 100-nucleotide 3' poly(A) tail. Single-dose, pre-filled syringe (0.5 mL)	• Acetic acid • Cholesterol • DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine) • SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate) • PEG2000-DMG (1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000) • Sodium acetate trihydrate • Sucrose • Trometamol • Trometamol hydrochloride • Water for injection

Description

mRESVIA is provided as a white to off-white, sterile, preservative-free, frozen dispersion for intramuscular injection. mRESVIA contains lipid nanoparticle (LNP), comprised of a messenger ribonucleic acid (mRNA) encoding the membrane-anchored RSV F glycoprotein stabilized in the prefusion confirmation, formulated with the non-medicinal ingredients listed in Table 2. mRESVIA does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials.

mRESVIA is supplied in a single-dose pre-filled syringe (polymeric barrel) with a plunger stopper and a rubber tip cap (without needle).

mRESVIA is available in the following package sizes:

- Carton of 1 single-dose pre-filled plastic syringe containing 1 dose of 0.5 mL
- Carton of 10 single-dose pre-filled plastic syringes, each syringe containing 1 dose of 0.5 mL.

7. Warnings and Precautions

General

As with other vaccines, vaccination with mRESVIA should be postponed in individuals suffering from an acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

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

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Driving and Operating Machinery

No studies on the effects of mRESVIA on the ability to drive and use machines have been performed. mRESVIA is unlikely to affect the ability to drive or use machines.

Hematologic

As with other vaccines administered intramuscularly, mRESVIA must be administered with caution to individuals with thrombocytopenia or a coagulation disorder since bleeding may occur following an intramuscular administration.

Immune

As with any vaccine, the administration of mRESVIA may not protect all vaccine recipients.

The safety and efficacy of mRESVIA have not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. These individuals may have a diminished immune response to mRESVIA.

7.1. Special Populations

7.1.1. Pregnancy

There are no data from the use of mRESVIA in pregnant women. mRESVIA is not recommended during pregnancy.

Pregnant women were excluded from enrolment in the clinical studies.

7.1.2. Breastfeeding

No human or animal data are available to assess the effects of mRESVIA on the breastfed infant or on milk production/excretion.

7.1.3. Pediatrics

The safety and efficacy of mRESVIA in children under 18 years of age have not been assessed in clinical trials.

7.1.4. Geriatrics

Clinical studies include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy of mRESVIA (see 8 Adverse Reactions and 14 Clinical Trials sections).

8. Adverse Reactions

8.1. Adverse Reaction Overview

Adults 60 Years of Age and Older

The safety profile of mRESVIA (Respiratory Syncytial Virus (RSV) mRNA Vaccine) presented below for participants 60 years of age and older is based on data generated from the safety analysis (median follow up of 8.6 months) of the ongoing pivotal Phase 2/3 randomized, placebo-controlled, observer-blind, multicentre clinical trial (Study 1: mRNA-1345-P301, NCT05127434) conducted in 22 countries

across 6 continents in both Northern and Southern Hemispheres with 54.9% participants from the United States and 2% from Canada. A total of 18,245 participants received mRESVIA (0.5 mL vaccine) and 18,184 received placebo (0.5 mL normal saline). Study participants are planned to be followed up for 24 months.

The most commonly reported (≥20%) adverse reactions were injection site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (25.6%), and arthralgia (21.7%).

Adults 18 Through 59 Years of Age

The safety profile of mRESVIA for adults 18 through 59 years of age at increased risk for LRTD caused by RSV is based on all safety data collected as of the data cutoff (median follow up of 253 days) of the Phase 3 randomized, double-blind clinical trial (Study 2: mRNA-1345-P303, NCT06067230) conducted in United States, Canada and the United Kingdom. A total of 502 study participants received 50 mcg dose of mRESVIA (approved dose) and 497 study participants received a lower 30 mcg dose of mRESVIA.

The most commonly reported (≥20%) adverse reactions were injection site pain (73.9%), fatigue (36.9%), headache (33.3%), myalgia (28.9%) and arthralgia (22.7%). Most solicited local and systemic adverse reactions had onset within 1 to 2 days after injection, and a median duration of 2 days.

8.2. Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reactions observed in the clinical trials may not reflect frequencies observed in clinical practice and should not be compared to frequencies reported in clinical trials of another drug.

The safety profile presented below is based on data generated in two clinical studies: Study 1: mRNA-1345-P301 in adults ≥ 60 years of age and Study 2: mRNA-1345-P303 in adults 18 through 59 years of age.

Adults 60 Years of Age and Older

At the time of vaccination in Study 1, the median age of the study participants was 67 years (range 60-96); 22,567 (61.9%) adults were 60-69 years of age, 10,975 (30.1%) adults were 70 to 79 years of age, and 2,887 (7.9%) adults were 80 years and older. Overall, 49.0% were female, 61.8% were White, 12.0% were Black, 11.0% were Asian, 14.7% were of other racial groups, and 33.6% were of Hispanic or Latino ethnicity. There were no notable differences in demographics or pre-existing medical conditions between participants who received mRESVIA and those who received placebo. The median duration of safety follow-up was 257 days (range 1 to 530 days), and 96.6% of participants had at least 6 months of follow-up after vaccination.

Solicited Adverse Reactions

Local and systemic adverse reactions (ARs) were solicited in an electronic diary for 7 days following injection (i.e., the day of injection and 6 subsequent days) among participants receiving mRESVIA (n=18,174) and participants receiving placebo (n=18,102). Events that persisted for more than 7 days were followed until resolution, but not to exceed 28 days after the study injection.

Overall, solicited adverse reactions (local and systemic) were reported for 68.1% of adults receiving mRESVIA versus 38.5% of adults receiving placebo. In adults receiving mRESVIA, most solicited local and systemic adverse reactions were mild [Grade 1 (46.7%)] or moderate [Grade 2 (15.3%)] in severity.

The most commonly (≥20%) reported solicited local adverse reaction was injection site pain, which was reported more commonly in mRESVIA recipients (55.9%) versus placebo recipients (13.8%) (see Table

3). The median onset was 2 days for local reactions post-vaccination with a duration of 1 to 2 days.

The most commonly (≥20%) reported solicited systemic adverse reactions were fatigue (30.8% in the mRESVIA group versus 20.0% in the placebo group), headache (26.7% versus 18.8%), myalgia (25.6% versus 14.4%), and arthralgia (21.7% versus 14.0%) (see Table 3). The median onset was 2 days for systemic reactions post-vaccination with median duration of 2 days. In both groups, most participants reported solicited adverse reactions (ARs) that were mild (Grade 1) or moderate (Grade 2). Severe (Grade 3) solicited ARs were reported for 5.9% of participants in the mRESVIA group versus 3.8% of participants in the placebo group.

The reported number and percentage of the solicited local and systemic adverse reactions of any grade and Grade 3 or higher are presented in Table 3.

Table 3 – Percentage of Study Participants with Solicited Local and Systemic Adverse Reactions of Any Grade and ≥Grade 3 within 7 Days* of Vaccination in Adults 60 Years of Age and Older (Safety Set of Study 1)

	mRESVIA (N=18,174) n (%)	**Placebo† (N=18,102) n (%)**
Local Adverse Reactions‡		
Injection Site Pain, Any Grade	10,161 (55.9)	2,498 (13.8)
Grade 3§	308 (1.7)	194 (1.1)
Axillary (underarm) swelling or tenderness, Any Grade	2,764 (15.2)	1,105 (6.1)
Grade 3§	138 (0.8)	116 (0.6)
Swelling (Hardness), Any Grade	673 (3.7)	61 (0.3)
Grade 3, >100 mm/>10 cm	156 (0.9)	18 (<0.1)
Erythema (Redness), Any Grade	364 (2.0)	103 (0.6)
Grade 3, >100 mm/>10 cm	106 (0.6)	59 (0.3)
Systemic Adverse Reactions		
Fatigue, Any Grade	5,589 (30.8)	3,618 (20.0)
Grade 3à	316 (1.7)	218 (1.2)
Headache, Any Grade	4,856 (26.7)	3,406 (18.8)
Grade 3β	277 (1.5)	209 (1.2)
Myalgia, Any Grade	4,655 (25.6)	2,610 (14.4)
Grade 3à	260 (1.4)	154 (0.9)
Arthralgia, Any Grade	3,948 (21.7)	2,541 (14.0)
Grade 3à	201 (1.1)	134 (0.7)
Chills, Any Grade	2,114 (11.6)	1,228 (6.8)
Grade 3ð	110 (0.6)	79 (0.4)
Nausea/vomiting, Any Grade	1,274 (7.0)	950 (5.3)
Grade 3è	80 (0.4)	75 (0.4)
Fever, Any Grade	502 (2.8)	235 (1.3)
≥Grade 3, ≥39.0°C/102.1°F	111 (0.6)	69 (0.4)

Any = Grade 1 or above; Percentages were based on the number of exposed participants who submitted any data for the event.

* 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).

† Placebo is 0.9% sodium chloride (normal saline) injection.
‡ No Grade 4 Solicited Local Adverse Reactions were reported.
§ Grade 3 injection site pain, axillary (underarm) swelling or tenderness: Defined as any use of prescription pain reliever; prevents daily activity.
β Grade 3 headache: Defined as Significant; any use of prescription pain reliever or prevents daily activity.
à Grade 3 fatigue, myalgia, and arthralgia: Defined as Significant; prevents daily activity.
è Grade 3 nausea/vomiting: Defined as prevents daily activity; requires outpatient intravenous hydration.
õ Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

Unsolicited Adverse Events

Participants were monitored for all unsolicited treatment emergent adverse events (TEAEs) up to 28 days following administration of mRESVIA or placebo. Unsolicited TEAEs considered related to the study vaccination were numerically higher in mRESVIA recipients (5.7%) than in in the placebo recipients (4.4%), primarily attributed to solicited adverse reactions that persisted beyond Day 7.

The incidence of hypersensitivity events was similar between the vaccine and placebo groups (0.6% and 0.5%, respectively). However, there was a numerically higher incidence of events of urticaria in the vaccine group (15 participants, <0.1%) with an onset ranging from 1-20 days post-vaccination with a duration ranging from 3-188 days compared with the placebo group (5 participants, <0.1%) with an onset ranging from 1-21 days post-vaccination with a duration ranging from 1-18 days.

The reported number and percentage of the unsolicited TEAEs with an incidence of ≥1% are presented in Table 4.

Table 4 – Summary of Unsolicited TEAEs with ≥ 1% incidence in Adults 60 Years of Age and Older – Onset up to 7 Days and Onset from 8 to 28 Days After Injection (Safety Set of Study 1)

System Organ Class Preferred Term	Onset Up to 7 Days				Onset from 8 to 28 Days			
	mRESVIA (N=18,245)		Placebo* (N=18,184)		mRESVIA (N=18,245)		Placebo* (N=18,184)	
	n	%	n	%	n	%	n	%
Number of Participants Reporting Unsolicited TEAEs	1,743	9.6	1,439	7.9	2,372	13.0	2,247	12.4
Infections and infestations	293	1.6	266	1.5	1,144	6.3	1,057	5.8
COVID-19	74	0.4	73	0.4	307	1.7	250	1.4
Nervous system disorders	278	1.5	227	1.2	148	0.8	153	0.8
Headache	241	1.3	205	1.1	71	0.4	54	0.3
Musculoskeletal and connective tissue disorders	531	2.9	476	2.6	256	1.4	273	1.5
Arthralgia	377	2.1	348	1.9	52	0.3	66	0.4
Myalgia	288	1.6	259	1.4	23	0.1	35	0.2

System Organ Class Preferred Term	Onset Up to 7 Days				Onset from 8 to 28 Days			
	mRESVIA (N=18,245)		Placebo* (N=18,184)		mRESVIA (N=18,245)		Placebo* (N=18,184)	
General disorders and administration site conditions	685	3.8	487	2.7	143	0.8	122	0.7
Fatigue	467	2.6	388	2.1	32	0.2	24	0.1

Abbreviations: N = number of participants; n/% = number/percentage of participants presenting with at least 1 unsolicited; TEAE=treatment emergent adverse event

* Placebo is 0.9% sodium chloride (normal saline) injection.

Serious Adverse Events and Adverse Events of Special Interest

Participants were monitored for all serious adverse events (SAEs) and protocol defined adverse events of special interest (AESI) throughout the study up to 24 months following administration of mRESVIA or placebo. A similar incidence of SAEs throughout the study was reported in both groups with 6.1% of mRESVIA recipients and 6.0% of placebo recipients. The incidence of AESIs was balanced between mRESVIA recipients and placebo recipients (0.2% for each group). One participant in the mRESVIA group had an SAE of facial paralysis with onset four days after vaccination; lasting 113 days (3.7 months), assessed as related to mRESVIA and requiring treatment. Within 28 days and 42 days post vaccination, there was no imbalance in reports of facial paralysis (including Bell's palsy) between treatment groups. There were no other notable patterns or numerical imbalances between treatment groups among categories of SAEs or AESIs that would suggest a causal relationship to mRESVIA.

Deaths and Adverse Events leading to Withdrawal from Study

Throughout the study following administration of mRESVIA or placebo, deaths and AEs leading to discontinuation were collected. Adverse events (AEs) leading to death were reported in 84 participants (0.5%) in the mRESVIA group and 83 participants (0.5%) in the placebo group. None of these deaths were assessed as related to study intervention. AEs leading to withdrawal from the study were similar in the mRESVIA and placebo groups: 99 (0.5%) and 105 (0.6%) participants, respectively. Most discontinuations in both groups were due to fatal events, as would be expected in a study of adults ≥60 years of age.

Adults 18 Through 59 Years of Age

The safety of mRESVIA was evaluated in Study 2 in which 999 participants aged 18 through 59 years at increased risk for LRTD caused by RSV received mRESVIA. 502 study participants received a 50 mcg dose of mRESVIA (approved dose) and 497 study participants received a lower 30 mcg dose. The study was conducted in the US, Canada and the United Kingdom.

The safety analysis for the study is provided based on all safety data collected as of the data cutoff. From the day of study injection (Day 1), the median duration of follow-up was 253 days (range: 8 to 349 days) in the safety set. As of the data cutoff date, 492/502 (98.0%) participants in the 50 mcg group and 488/497 (98.2%) participants in the 30mcg group had completed at least 180 days of post-injection follow-up.

In Study 2, the median age of the participants in the safety set was 52.0 years (range: 19 to 59 years). Overall, 52.7% participants were female, 78.5% were White, 17.7% were Black, 1.7% were Asian, 1.6% were of other racial groups, and 28.4% were of Hispanic or Latino ethnicity.

Based on the Safety Set, eligible participants enrolled in the study had multiple clinically stable conditions that increased their risk for developing RSV-LRTD. Overall, diabetes mellitus (DM) was reported in 57.8% of participants, persistent asthma in 38.8%, coronary artery disease (CAD) in 20.1%, chronic obstructive pulmonary disease (COPD) in 10.3%, congestive heart failure (CHF) in 9.8%, and chronic respiratory disease other than COPD or asthma in 3.0%. Additionally, 62.2% of participants had a BMI of 30 kg/m² or higher, indicating a significant prevalence of obesity within the study population.

Solicited Adverse Reactions

Reactogenicity was assessed using a prespecified list of local and systemic adverse reaction terms that were actively solicited daily via eDiaries during the 7 days following injection (i.e., the day of injection and 6 subsequent days). The reported frequencies of specific solicited local and systemic adverse reactions among participants 18 through 59 years of age at increased risk for LRTD caused by RSV who received mRESVIA are presented in Table 5.

Most solicited local and systemic adverse reactions had onset within 1 to 2 days after injection, and a median duration of 2 days.

Table 5 – Percentage of Study Participants with Solicited Local and Systemic Adverse Reactions of Any Grade and ≥Grade 3 within 7 Days* of Vaccination in Adults 18 to 59 Years of Age and Older (Safety Set of Study 2)

	mRESVIA 50-mcg dose (N=502) n (%)
Local Adverse Reactions	
Injection Site Pain, Any Grade	371 (73.9)
Grade 3 or Grade 4[†]	8 (1.6)
Axillary (underarm) swelling or tenderness, Any Grade[‡]	86 (17.1)
Grade 3[‡]	3 (0.6)
Erythema (Redness), ≥ 2.5 cm	12 (2.4)
Swelling (Hardness), ≥ 2.5 cm	23 (4.6)
Grade 3, >10 cm	1 (0.2)
Systemic Adverse Reactions	
Fever, Any Grade	18 (3.6)
Grade 3, ≥39.0°C/102.1°F	3 (0.6)
Headache, Any Grade[§]	167 (33.3)
Grade 3[§]	8 (1.6)
Fatigue, Any Grade[à]	185 (36.9)
Grade 3[à]	14 (2.8)
Myalgia, Any Grade[β]	145 (28.9)
Grade 3[β]	11 (2.2)
Arthralgia, Any Grade[β]	114 (22.7)
Grade 3[β]	10 (2.0)
Nausea/vomiting, Any Grade[¶]	54 (10.8)
Chills, Any Grade[#]	100 (19.9)
Grade 3[#]	4 (0.8)

Abbreviations: Any = Grade 1 or above; Percentages were based on the number of exposed participants who submitted any data for the event.

N = number of vaccinated participants with available data for the events listed.

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

† Injection site pain grading scale: Does not interfere with activity (Grade 1); repeated use of over-the-counter pain reliever >24 hours or interferes with activity (Grade 2); any use of prescription pain reliever or prevents daily activity (Grade 3); requires emergency room visit or hospitalization (Grade 4).

‡ Axillary (underarm) swelling or tenderness grading scale: No interference with activity (Grade 1); repeated use of over-the-counter pain reliever >24 hours or some interference with activity (Grade 2); any use of prescription pain reliever or prevents daily activity (Grade 3).

§ Headache grading scale: No interference with activity (Grade 1); repeated use of over-the-counter pain reliever >24 hours or some interference with activity (Grade 2); significant, any use of prescription pain reliever or prevents daily activity (Grade 3).

à Fatigue grading scale: No interference with activity (Grade 1); some interference with activity (Grade 2); significant, prevents daily activity (Grade 3).

β Myalgia and arthralgia grading scales: No interference with activity (Grade 1); some interference with activity (Grade 2); significant, prevents daily activity (Grade 3).

¶ Nausea/vomiting grading scale: No interference with activity or 1-2 episodes per 24 hours (Grade 1); some interference with activity or >2 episodes per 24 hours (Grade 2); prevents daily activity, requires outpatient intravenous hydration (Grade 3).

Chills grading scale: No interference with activity (Grade 1); some interference with activity not requiring medical intervention (Grade 2); prevents daily activity and requires medical intervention (Grade 3).

Unsolicited Adverse Events

The unsolicited AEs with an incidence rate ≥ 1% reported up to 28 days after injection in the 50 mcg group were all common infections: upper respiratory tract infection (3.2%), rhinovirus infection (1.8%), nasopharyngitis (1.8%), and COVID-19 (1.6%).

Serious Adverse Events and Adverse Events of Special Interest

Overall, by the data cutoff, serious adverse events were reported for 19 participants (3.8%) in the 50 mcg group. One participant with multiple confounding underlying medical conditions and who received a lower dose of the investigational vaccine had an SAE and AESI of Bell's palsy on Day 43. Given the presence of multiple confounding factors and the onset past the 6-week risk window, there was insufficient information to indicate a potential causal association with the study injection. No notable patterns in SAEs or AESIs were observed in either treatment group that would suggest a causal relationship or trend associated with mRESVIA.

Deaths and Adverse Events leading to Withdrawal from Study

Up to the DCO there were no deaths or AEs leading to study discontinuation assessed by the investigator as related to the study injection

9. Drug Interactions

9.1. Serious Drug Interactions

No interaction studies have been performed.

If mRESVIA is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites. Do not mix mRESVIA with other vaccines/products in the same syringe.

As studies are ongoing, concomitant administration of mRESVIA with other vaccines are unknown.

10. Clinical Pharmacology

10.1. Mechanism of Action

mRESVIA is an mRNA-based vaccine encoding the membrane-anchored RSV F glycoprotein stabilized in the prefusion conformation through changes to the amino acid sequence. The F protein exists in two primary conformational states, prefusion and post-fusion. The prefusion state facilitates entry into the host cell through a conformational change to the post-fusion state. The prefusion F glycoprotein is the target of potent neutralising antibodies that mediate protection against RSV associated respiratory tract disease.

mRESVIA stimulates production of RSV A and RSV B neutralising antibodies and induction of antigen-specific cellular immune responses.

11. Storage, Stability, and Disposal

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

Frozen Storage

Store frozen between -40°C to -15°C for up to 18 months.

Once thawed, the vaccine should not be refrozen.

Storage after Thawing

Store in a refrigerator between 2°C and 8°C.

Within the 18-month shelf life, the unopened vaccine may be stored refrigerated between 2°C and 8°C, protected from light, for a maximum of 90 days.

Unopened pre-filled syringes may be stored at 8°C to 25°C for a total of 24 hours after removal from refrigerated conditions.

Thawed pre-filled syringes can be handled in room light conditions.

12. Special Handling Instructions

Do not dilute the product.

Do not shake the pre-filled syringe.

mRESVIA dispersion for injection does not contain a preservative, is for single use, and should be administered immediately after uncapping.

mRESVIA must not be mixed with other medicinal products or diluted. Any unused mRESVIA should be disposed of in accordance with local requirements.

Part 2: Scientific Information

13. Pharmaceutical Information

Drug Substance

Proper name: Respiratory Syncytial Virus (RSV) mRNA Vaccine

Medicinal ingredient: mRNA encoding RSV glycoprotein F stabilized in the prefusion conformation, 5'(m7G-5'-ppp-5'-Gm) cap, 100-nucleotide 3' poly(A) tail

Product Characteristics:

mRESVIA is manufactured with a cell-free process; mRNA, which includes a 5' cap and poly(A) tail, is transcribed in vitro from a DNA template encoding the membrane-anchored RSV fusion (F) glycoprotein stabilized in the prefusion conformation and purified.

mRESVIA is supplied as a sterile single-dose, ready-to-use liquid solution at 50 mcg/0.5 mL for intramuscular (IM) administration in a 1-mL pre-filled syringe (PFS).

14. Clinical Trials

14.1. Clinical Trials by Indication

Efficacy in Adults 60 Years of Age and Older

Table 6 – Summary of patient demographics for clinical trials in adults 60 years and older

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
Study 1: mRNA-1345-P301 (NCT05127434)	Phase 2/3, randomized, observer-blind, placebo-controlled case-driven clinical study	1 dose of mRESVIA, intramuscular injection, month 0	36,557 total; 706 Canadian participants (18,304 mRESVIA; 18,253 Placebo)	68.5 years (60 to 108)	Females: 49.0% Males: 51.0%

Study 1 is an ongoing randomised, placebo-controlled, observer-blind Phase 2/3 case driven clinical study to evaluate the safety and efficacy of mRESVIA to prevent RSV-LRTD in adults 60 years of age or older with or without underlying medical conditions for up to a year after single vaccination with mRESVIA.

Study 1 is being conducted in 22 countries and includes participants from North America/ Europe, Central/Latin America, Africa, and Asian/Pacific regions and is designed to follow participants for up to 24 months after vaccination.

Participants were randomised to a single injection of mRESVIA or placebo (in a 1:1 ratio). Randomisation was stratified by age (60 to 74 years; ≥ 75 years) and risk factors for LRTD, which were defined as congestive heart failure (CHF) and/or chronic obstructive pulmonary disease (COPD) at screening.

The primary efficacy analysis population (referred to as the Per-Protocol Efficacy Set), included 35,088 subjects who received either mRESVIA (n=17,572) or placebo (n=17,516) with a data cutoff of 30 November 2022. This study population included 49.1% female, 63.5% White, 12.2% Black, 8.7% Asian, 15.7% of other racial groups. Thirty five percent (35%) of participants identified as Hispanic or Latino. The median age of subjects was 67 years (range 60 to 96), with 30.9% of participants between 70 and 79 years and 5.5% of participants ≥80 years. There were no notable differences in demographics or pre existing medical conditions between participants who received mRESVIA and those who received placebo. A total of 6.9% had protocol defined LRTD risk factors (CHF and/or COPD) and 29.3% had one or more comorbidity of interest (COPD, asthma, chronic respiratory disease, diabetes, CHF, advanced liver disease, or advanced renal disease). A total of 21.8% of the Per Protocol Efficacy Set (PPE) scored "vulnerable" or "frail" according to Edmonton Frail Scale. Of those participants 16.1% were assessed as "vulnerable", 4.6% as having mild frailty, 0.9% as having moderate frailty, and 0.2% as having severe frailty.

Study 1 exclusion criteria included history of myocarditis, pericarditis, or myopericarditis within 2 months prior to screening; autoimmune conditions requiring systemic immunosuppressants (stable HIV positive participants were permitted); history of serious reaction to any prior vaccination. Individuals were not eligible if they received any other vaccine within 28 days before or after administration of the study injection.

The primary efficacy endpoints were the prevention of a first episode of RSV-associated lower respiratory tract disease (RSV-LRTD) with ≥2 or ≥3 signs/symptoms between 14 days and 12 months post-injection. RSV LRTD was defined based on the following criteria: The participant must have had RT PCR confirmed RSV infection and experienced new or worsening of 2 or more (or 3 or more) of the following signs/symptoms for at least 24 hours: shortness of breath, cough and/or fever (≥37.8°C), wheezing and/or rales and/or rhonchi, sputum production, tachypnea (≥20 breaths per minute or increase of ≥2 breaths per minute from baseline measurement in those who have baseline tachypnea), hypoxemia (new oxygen saturation ≤93% or new or increasing use of supplemental oxygen), or pleuritic chest pain. If signs/symptoms could not be captured, radiologic evidence of pneumonia with RT-PCR-confirmed RSV infection was also counted as RSV-LRTD.

Study 1 Results

The primary efficacy endpoints were defined as the prevention of a first episode of RSV LRTD with either ≥ 2 sign/symptoms starting 14 days postinjection. Efficacy was evaluated after a median of 3.7 months of follow-up (range 15 to 379 days), when at least 50% of targeted RSV-LRTD cases had accrued. Both primary efficacy endpoints met the predefined success criterion (lower bound of the alpha-adjusted CI of the VE was >20%). Additional analyses of efficacy were performed after a median of 8.6 months of follow-up (range 15 to 530 days) when 94.3% of participants had reached 6 months of follow-up after vaccination and lower bound of the 95% CI of the VE was >20%.

Vaccine efficacy results are shown in Table 7.

Table 7 – Primary Analyses of VE of mRESVIA to Prevent First Occurrence of Protocol Defined RSV-LRTD with 2 or More and 3 or More Signs/Symptoms Between 14 Days After Injection Up to 12 Months Post Injection Efficacy of mRESVIA to Prevent First Episode of Proto

Primary Analyses 3.7 months median follow-up	**mRESVIA (N=17,572) n (%)**	**Placebo (N=17,516) n (%)**	**Vaccine Efficacy* Based on Hazard Ratio (%) (% CI) †**
RSV-LRTD with ≥2 Signs/Symptoms	9 (0.05)	55 (0.31)	83.7 (66.0, 92.2)
RSV-LRTD with ≥3 Signs/Symptoms	3 (0.02)	17 (0.10)	82.4 (34.8, 95.3)
Additional Analyses 8.6 months median follow-up	**mRESVIA (N=18,112) n (%)**	**Placebo (N=18,045) n (%)**	**Vaccine Efficacy* Based on Hazard Ratio (%) (95% CI) †**
RSV-LRTD with ≥2 Signs/Symptoms	47 (0.26)	127 (0.70)	63.3 (48.7, 73.7)
RSV-LRTD with ≥3 Signs/Symptoms	19 (0.10)	51 (0.28)	63.0 (37.3, 78.2)

Abbreviations: CI = Confidence Interval; RSV-LRTD = Respiratory Syncytial Virus Lower Respiratory Tract Disease. Stratification factors at randomization are Age Group (60 to 74 years or 75 years and older) and LRTD Risk (Present or Absent).

* Vaccine efficacy (VE) is defined as 100% x (1 - hazard ratio (mRNA-1345 vs. placebo)). The CI for VE is based on a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a fixed effect, adjusting for stratification factors at randomization.

† For primary analysis for RSV-LRTD with 2 or more symptoms, 95.88% CI where the alpha value of 4.12% was derived from the Lan-DeMets approximation to the Pocock stopping boundary with an information fraction of 0.74 (64 out of total of 86 cases). For primary analysis for RSV-LRTD with 3 or more symptoms, 96.36% CI where the alpha value of 3.64% was derived from the Lan-DeMets approximation to the Pocock stopping boundary with an information fraction of 0.63 (20 out of total of 32 cases).

Descriptive vaccine efficacy analyses by age subgroup, for participants with at least one comorbidity considering frailty status are presented in Table 8.

Table 8 – Efficacy of mRESVIA to Prevent First Episode of RSV-LRTD (With 2 or More Signs/Symptoms) by Subgroup (8.6 Months Median Follow-up, Per-Protocol Efficacy Set)

Subgroup	**mRESVIA Cases, n/N***	**Placebo Cases, n/N***	**VE**, %**
60 to 69 years	31/11,219	77/11,170	60.1
70 to 79 years	10/5,464	45/5,439	78.0
≥80 years	6/1,429	5/1,436	N/A†
≥60 years with ≥1 comorbidity‡	16/5,361	51/5,249	69.3
≥60 years considered Vulnerable/Frail ≥4§	9/3,817	17/3,884	46.5

Abbreviations: RSV LRTD=respiratory syncytial virus-associated lower respiratory tract disease

* Based on the number of participants in each subgroup (N1).

** VE is based on an exploratory analysis, subject to limitations.

† N/A = not applicable due to low number of total cases accrued in this subgroup.

‡ Comorbidities included in this analysis were chronic cardiopulmonary conditions, including CHF, COPD, asthma and chronic respiratory conditions as well as diabetes, advanced liver, and advanced kidney disease.

§ According to the Edmonton Frail Scale.

As shortness of breath is associated with more severe RSV disease, an exploratory analysis was conducted. Among 174 cases of RSV-LRTD with 2 or more signs/symptoms, a total of 54 cases of RSV-LRTD with shortness of breath occurred: 43 in placebo recipients and 11 in mRESVIA recipients.

Immunogenicity in Adults 18 to 59 Years of Age at Increased Risk for LRTD Caused by RSV

Table 9 – Summary of patient demographics for the clinical trial in adults 18 to 59 years of age at increased risk for LRTD caused by RSV

Study #	Study design	Dosage, route of administration and duration	Study subjects* (n)	Mean age (Range)	Sex
Study 2: mRNA-1345-P303 (NCT06067230)	Phase 3, randomized, double-blind clinical study	1 dose of mRESVIA, intramuscular injection, month 0	501 total; 39 Canadian participants (501 mRESVIA)	49.6 years (19 to 59)	Females: 53.5% Males: 46.5%

* Randomized Set

Study 2 is a Phase 3 randomized, double-blind trial to evaluate the immunogenicity and safety of mRESVIA in adults aged 18 through 59 years at increased risk for LRTD caused by RSV. Effectiveness of mRESVIA in this population is inferred based on immunobridging neutralizing antibody (nAb) levels at Day 29 to those observed in Study 1 conducted in adults ≥60 years of age.

Adults who had documented confirmation of at least one of the following conditions were enrolled: coronary artery disease and/or CHF, chronic lung disease (including but not limited to COPD or persistent asthma), or Type 1 or Type 2 diabetes mellitus. 502 participants received 50 mcg of mRESVIA.

Study 2 Results

The co-primary immunogenicity objectives of Study 2 were to evaluate nAb responses after a single dose of 50 mcg mRESVIA, using the geometric mean ratio (GMR) as the key measure. Noninferiority of nAb levels at Day 29 (for RSV-A and RSV-B) for Study 2 were compared to those of the Study 1 Per Protocol Immunogenicity (PPI) Set. Noninferiority was successfully met – and effectiveness was inferred – if the lower bound of the 95% CI of the GMR was >0.667.

The co-primary immunogenicity endpoints (GMR) were assessed by measuring nAb geometric mean titer (GMT) at Day 29 (against RSV-A and RSV-B) after a single dose of 50-mcg mRESVIA in the Study 2 PP Set. These responses in Study 2 participants were compared with those in Study 1 to determine the GMR.

The GMR (95% CI) at Day 29 was 1.163 (1.053, 1.285) and 1.135 (1.037, 1.242) for RSV-A and RSV-B, respectively (Table 10). Results met prespecified Study 2 noninferiority criteria for the co-primary objectives and allow the effectiveness of a single dose of 50 mcg mRESVIA to be inferred in adults 18 through 59 years at increased risk for RSV-LRTD.

Table 10 – Comparison of Model-Adjusted Day 29 RSV Neutralizing Antibody GMT and GMR from Study 2 in Adults 18 through 59 Years of Age at Increased Risk of LRTD Caused by RSV and Study 1 in Adults 60 Years of Age and Older

	mRESVIA Study 2 (50-mcg PP Set*) (N=494)			mRESVIA Study 1 (50-mcg PPI Set#) (N=1,515)			Study 2 versus Study 1	
RSV subtype	N1	Model-Based GMT[a]	95% CI	N1	Model-Based GMT[a]	95% CI	GMR	95% CI
RSV-A	492	23245.01	(21326.32, 25336.34)	1513	19988.17	(19038.32, 20985.41)	1.163	(1.053, 1.285)
RSV-B	489	7830.71	(7242.04, 8467.23)	1511	6901.15	(6602.51, 7213.30)	1.135	(1.037, 1.242)

PP=Per-Protocol; PPI=Per-Protocol Immunogenicity; GMT = Geometric Mean Titer (IU/ml); GMR = Geometric Mean Ratio

N1 = Number of participants with non-missing antibody data at baseline (Day 1) and Day 29.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ.

* The PP Set consisted of all participants who received the study injection, had no significant protocol deviations that impacted the immune responses, and had pre-injection baseline and at least one post-injection assessment occurring between 14 and 42 days after injection.

The PPI Set consisted of a randomly selected subset of participants who received the study injection, had no significant protocol deviations that impacted the immune responses, and had both pre-injection baseline and post-injection Day 29 assessments.

[a] The model-based GMT is estimated on Analysis of covariance (ANCOVA) model. In the ANCOVA model, the log-transformed antibody levels at Day 29 post baseline are treated as a dependent variable, with the treatment group as an explanatory variable and the log-transformed baseline antibody level as a covariate. The resulted least square (LS) means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.

Seroresponse Rate Difference between Study 2 and Study 1 for Day 29 nAb (RSV-A and RSV-B)

Seroresponse at a participant level was defined as a change from below the LLOQ to equal or above 4 x LLOQ, or at least a 4-fold increase if baseline is equal to or above the LLOQ. The seroresponse rate (SRR) difference at Day 29 between Study 2 and Study 1 groups for RSV A was 11.8% (95% CI: 7.8, 15.5) and for RSV-B was 10.8% (95% CI: 5.9, 15.6). The 95% CI was calculated using the Miettinen-Nurminen (score) confidence limits. Accordingly, the difference in SRR for both RSV-A and RSV-B met prespecified non-inferiority success criteria of the lower bound of the 95% CI >-10% in adults 18 through 59 years at increased risk for RSV-LRTD who received 50 mcg of mRESVIA.

15. Microbiology

No microbiological information is required for this vaccine.

16. Non-Clinical Toxicology

General toxicology: Non-clinical data reveal no special hazards for humans based on repeated dose toxicity studies in rats.

Genotoxicity: mRNA-1345 has not been evaluated for carcinogenic, mutagenic potential, or impairment of male fertility in animals.

Reproductive and developmental toxicology: A developmental toxicity study was conducted in female rats that received 96 mcg mRNA-1345 twice prior to mating and twice during gestation, which is a dose level in excess of a single human dose level of mRNA-1345. No impact on female fertility, fetal development or postnatal development was reported. Impacts on milk production or excretion and presence of the test article in milk were not evaluated.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

mRESVIA™

Respiratory Syncytial Virus (RSV) mRNA Vaccine; Dispersion for intramuscular injection

This Patient Medication Information is written for the person who will be receiving **mRESVIA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **mRESVIA**, talk to a healthcare professional.

What mRESVIA is used for:

mRESVIA is a vaccine to help protect you against lower respiratory tract disease (LRTD) caused by RSV.

mRESVIA is for people 60 years of age and older, and also for people 18 through 59 years of age who are at increased risk for RSV (people with medical conditions which include, but are not limited to, diabetes or with diseases affecting the lungs, and heart).

How mRESVIA works:

mRESVIA works by causing the body to produce its own protection (antibodies) against RSV. mRESVIA uses a molecule called messenger ribonucleic acid (mRNA, the genetic code for a piece of the virus) to deliver the set of instructions that cells in your body can use to make antibodies to help fight the virus that causes RSV.

As mRESVIA does not contain the RSV virus, it cannot cause an RSV infection.

As with all vaccines, mRESVIA may not fully protect all people who receive the vaccine.

The ingredients in mRESVIA are:

Medicinal ingredient(s): one 0.5 mL dose of mRESVIA contains 50 micrograms of mRNA encoding RSV glycoprotein F stabilized in the prefusion conformation

Non-medicinal ingredients:

- acetic acid
- cholesterol
- DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine)
- SM-102 (Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate)
- PEG2000-DMG (1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000)
- sodium acetate trihydrate
- sucrose
- trometamol
- trometamol hydrochloride
- water for injection

mRESVIA comes in the following dosage form(s):

mRESVIA is available as a dispersion for intramuscular injection. mRESVIA comes in a single-dose (0.5 mL) pre-filled syringe.

Do not receive mRESVIA if:

You are allergic (hypersensitive) to any of the ingredients contained in mRESVIA (see The ingredients in mRESVIA are). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take mRESVIA. Talk about any health conditions or problems you may have, including if you:

- have a severe infection with a high temperature. In these cases, the vaccination may be postponed until recovery. A minor infection such as a cold, including mild fever, should not be a problem, tell your healthcare professional first
- had a severe allergic reaction after receiving a previous dose of any vaccine, including those against RSV infection
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have ever fainted in association with an injection or before receiving any needle injection
- have a bleeding disorder or are on a blood thinner

Other warnings you should know about:

- Do not drive or use machines if you are feeling unwell.

Pediatrics (< 18 years of age):

- mRESVIA is not indicated for use in infants, children and adolescents under 18 years old.

Pregnancy and breast-feeding:

- There is no information on the use of mRESVIA in pregnant or breast-feeding women.
- mRESVIA is not recommended for use in pregnancy.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There is limited information on the use of mRESVIA with other vaccines. Tell your healthcare professional if you have recently received any other vaccine.

How to take mRESVIA:

Your doctor, pharmacist or nurse will inject the vaccine into a muscle.

If mRESVIA is given at the same time as another vaccine, a different injection site will be used for each vaccine.

Usual dose:

mRESVIA is given as a single dose of 0.5 mL as an injection.

Overdose:

If you think you, or a person you are caring for, have taken too much mRESVIA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Possible side effects from using mRESVIA:

Like all vaccines, mRESVIA can cause side effects, although not everyone gets them.

The following side effects may occur after receiving mRESVIA. Most of these side effects are mild and do not last long. These are not all the possible side effects you may have when taking mRESVIA.

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- pain at the injection site
- fatigue
- chills
- headache
- swelling of lymph nodes
- muscle pain and joint pain

Common (these may occur with up to 1 in 10 doses of the vaccine):

- redness and swelling at the injection site
- swelling of lymph nodes
- fever
- nausea and vomiting

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting suspected side effects for vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada (PHAC), Health Canada (HC), and Moderna Biopharma Canada Corp. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (Reporting Adverse Events Following Immunization (AEFI) in Canada) and send it to your local Health Unit.

Storage:

Your doctor or pharmacist is responsible for storing, supplying and administering mRESVIA, as well as disposing of any unused product correctly.

Keep out of reach and sight of children.

If you want more information about mRESVIA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website www.modernatx.com/en-CA; or by calling 1-866-MODERNA [1-866-663-3762].

This leaflet was prepared by Moderna Biopharma Canada Corporation.

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