swissmedic

Date: 17 November 2026
Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report
Extension of therapeutic indication

mResvia
Respiratory syncytial virus mRNA vaccine

International non-proprietary name:	mRNA-1345, a single-stranded 5' capped mRNA (messenger RNA) encoding the RSV-A glycoprotein F stabilised in the prefusion conformation
Pharmaceutical form:	Dispersion for injection in pre-filled syringe
Dosage strength(s):	50 µg/0.5 mL
Route(s) of administration:	Intramuscular injection
Marketing authorisation holder:	Moderna Switzerland GmbH
Marketing authorisation no.:	69995
Decision and decision date:	extension of therapeutic indication approved on 16 September 2026

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

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1 Terms, Definitions, Abbreviations

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
API	Active pharmaceutical ingredient
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	Area under the plasma concentration-time curve for the 24-hour dosing interval
CI	Confidence interval
C_{max}	Maximum observed plasma/serum concentration of drug
CYP	Cytochrome P450
DDI	Drug-drug interaction
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GI	Gastrointestinal
GLP	Good Laboratory Practice
HPLC	High-performance liquid chromatography
IC/EC_{50}	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing authorisation holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Background information on the procedure

2.1 Applicant's request(s) and information regarding procedure

Extension(s) of the therapeutic indication(s)
The applicant requested the addition of a new therapeutic indication or modification of an approved indication in accordance with Article 23 TPO.

Authorisation as human medicinal product in accordance with Article 13 TPA
The applicant requested a reduced assessment procedure in accordance with Article 13 TPA.

2.2 Indication and dosage

2.2.1 Requested indication

mRESVIA is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in adults 18 years of age and older.
The use of this vaccine should be in accordance with official recommendations.

2.2.2 Approved indication

mRESVIA is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in adults 18 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

2.2.3 Requested dosage

No change to the dosage recommendation was requested with the application for extension of indication.

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	20 April 2026
Formal control completed	23 April 2026
Preliminary decision	12 August 2026
Response to preliminary decision	18 August 2026
Final decision	16 September 2026
Decision	approval

Based on Art. 13 TPA Swissmedic has not assessed the primary data (e.g., study reports) submitted with this application and relies for its decision on the assessment of the foreign reference authority EMA. This SwissPAR relates to the assessment mResvia (EMADOC-1700519818-3003237; Procedure No. EMA/VR/ 0000312911, published on 30 April 2026) issued by EMA.

3 Clinical aspects

Swissmedic has not assessed the primary data relating to clinical aspects submitted with this application and relies on the assessment of the foreign reference authority EMA (see section 2.3 Regulatory history (milestones)).

4 Risk management plan summary

The RMP summaries contain information on the medicinal products' safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.
The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

5 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for mResvia was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo-pro.ch).

Note:
The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. See the "Undesirable effects" section for advice on the reporting of adverse reactions. The following product information will be regularly updated as soon as new data and safety reports are available.

mRESVIA dispersion for injection in pre-filled syringe
Respiratory Syncytial Virus mRNA Vaccine

Composition

Active substances

Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified) contains as active substance a single-stranded 5’ capped mRNA (*messenger RNA*) encoding the RSV-A glycoprotein F stabilised in the prefusion conformation. The mRNA is encapsulated in lipid nanoparticles.

Excipients

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

Each 0.5 ml dose contains 0.017 mg sodium.

Pharmaceutical form and active substance quantity per unit

Dispersion for injection in pre-filled syringe.
White to off-white dispersion (pH: 7.0 – 8.0).
Each single-dose pre-filled syringe contains 0.5 ml of the vaccine.

One dose (0.5 ml) contains 50 µg of Respiratory Syncytial Virus (RSV) mRNA (nucleoside modified) encapsulated in lipid nanoparticles.

Indications/Uses

mRESVIA is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) inadults 18 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Dosage/Administration

This medicinal product should be administered by a trained healthcare professional using aseptic techniques to ensure sterility.

Posology

The recommended dose of mRESVIA is one single dose of 0.5 ml.
A revaccination dose (0.5 ml) may be administered at least 12 months after vaccination with an RSV vaccine (see section “Properties/Effects”).

Method of administration

For intramuscular injection only.

mRESVIA should be administered preferably in the deltoid muscle of the upper arm. The injection should be given using standard aseptic technique.

The vaccine must not be injected intravenously, subcutaneously or intradermally.

The vaccine should not be mixed with any other vaccines or medicinal products in the same syringe.

For instructions for preparation of the medicinal product before administration and special handling requirements, see section “Other information”.

Traceability

To ensure traceability of biotechnological medicinal products, it is recommended that the trade name and batch number should be documented for each treatment.

Special dosing instructions

Children and adolescents

mRESVIA is not indicated for use in the paediatric population.

mRESVIA is contraindicated in children younger than 8 months of age because of an increased risk of RSV enhanced respiratory disease (see sections “Contraindications” and “Undesirable effects”). The safety and efficacy of mRESVIA in children (from 8 months to less than 18 years of age) have not yet been established. No data are available.

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section “Composition”.
Children less than 8 months of age because of an increased risk of severe and life-threatening RSV enhanced respiratory disease (see sections “Posology and method of administration” and “Undesirable effects”).

Warnings and precautions

Hypersensitivity and anaphylaxis

Appropriate medical treatment and supervision should always be readily available in case of a severe hypersensitivity reaction, including anaphylaxis, following administration of the vaccine.

Anxiety-related reactions

Anxiety-related reactions including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute infection or febrile illness. The presence of a minor infection, such as a cold, should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

The safety and immunogenicity of mRESVIA have been assessed in immunocompromised individuals. Some individuals may have a diminished immune response to this vaccine (see sections “Undesirable effects” and “Properties/Effects”).

Limitations of vaccine effectiveness

As with all vaccines, vaccination with mRESVIA may not protect all vaccine recipients.

Excipients with known effect

Sodium

This vaccine contains less than 1 mmol sodium (23 mg) per 0.5 ml dose, that is to say essentially “sodium-free”.

Interactions

Use with other vaccine

mRESVIA can be administered concomitantly with:

- seasonal influenza vaccines, either standard dose or high dose unadjuvanted
- COVID-19 mRNA vaccine

Pregnancy, lactation

Pregnancy

There are no or limited amount of data from the use of mRESVIA in pregnant women. Animal studies with mRESVIA do not indicate direct or indirect harmful effects with respect to pregnancy (see section “preclinical safety data”). As a precautionary measure, it is preferable to avoid the use of mRESVIA during pregnancy.

Lactation

It is unknown whether mRESVIA is excreted in human milk.

Fertility

No human data on the effect of mRESVIA on fertility are available.

Animal studies with mRESVIA do not indicate direct or indirect harmful effects with respect to female reproductive toxicity. Animal studies are insufficient to assess male reproductive toxicity (see section “preclinical safety data”).

Effects on ability to drive and use machines

mRESVIA has no or negligible influence on the ability to drive and use machines.

However, some of the effects mentioned under section “Undesirable effects” (e.g., fatigue, dizziness) may temporarily affect the ability to drive or use machines.

Undesirable effects

Summary of the safety profile

The safety profile and the frequencies of adverse reactions presented below are based on data generated in three clinical studies: Study 1 in adults ≥ 60 years of age (n=18 245), Study 2 in adults 18 through 59 years of age (n=502) and Study 3 in immunocompromised adults 18 years of age and older (n=150).

Individuals 60 years of age and older

In Study 1, which enrolled individuals 60 years of age and older, the most commonly reported adverse reactions were injection site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (25.6%) and arthralgia (21.7%). The onset of most solicited local and systemic adverse reactions was within 1 to 2 days after injection and resolved within 1 to 2 days after onset. The majority of local and systemic solicited adverse reactions were mild in intensity.

Individuals 18 through 59 years of age

In Study 2, which enrolled individuals 18 through 59 years of age at increased risk for LRTD caused by RSV, the most commonly reported 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.

Immunocompromised individuals 18 years of age and older

In Study 3, which enrolled individuals 18 years of age and older who had previously undergone solid organ transplant (SOT) procedures (kidney, liver or lung), reactogenicity after one or two doses was consistent with the known profile of mRESVIA. There were no unexpected safety findings.

Tabulated list of adverse reactions

Adverse reactions reported are listed according to the following frequency convention:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1 000)
Very rare (<1/10 000)

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness (

Table **1**).

Table 1. Adverse reactions following administration of mRESVIA

MedDRA system organ class	Frequency	Adverse reaction(s)
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Uncommon	Hypersensitivity
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness
	Rare	Peripheral facial nerve paralysis (e.g., Bell's palsy)†
Gastrointestinal disorders	Very common	Nausea/vomiting‡
Skin and subcutaneous tissue disorders	Rare	Urticaria§
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills
	Common	Pyrexia Injection site erythema Injection site swelling/induration
	Rare	Injection site pruritus

* Lymphadenopathy was collected as "Axillary (underarm) swelling or tenderness ipsilateral to the side of injection".
In study 1, one participant in the vaccine group had a serious adverse event of facial paralysis with onset on Day 5. Within the 42-day risk window following injection, Bell's palsy and/or facial paralysis was reported by 2 participants in the mRESVIA group and 2 participants in the placebo group. All 4 of these participants had risk factors for Bell's palsy. In Study 2, one participant who had multiple confounding underlying medical conditions and received a lower dose of the investigational vaccine had an SAE of Bell's palsy on Day 43.
‡ Reported as common in individuals 60 years of age and older (Study 1).
§ Urticaria has been observed with either acute onset (within a few days after vaccination) or delayed onset (up to approximately two weeks after vaccination) and may be acute or chronic (≥ 6 weeks) in duration.

Infants less than 8 months of age

In a paediatric clinical study, there was a higher proportion of severe RSV infections in children immunized between 5 to less than 8 months of age with mRESVIA or an investigational vaccine containing mRESVIA components compared to placebo. This risk of RSV enhanced respiratory disease is not applicable to adults (see sections “Posology and method of administration” and “Contraindications”).

Adults (revaccination)

The safety and reactogenicity of a revaccination dose of mRESVIA were evaluated in three phase 3 studies (see section “Properties/Effects”). In study 4C (n=543), participants ≥50 years of age who had previously received a single dose of mRESVIA received a revaccination dose at 12 months after primary vaccination with mRESVIA. In study 1B (n=998), participants ≥60 years of age who had previously received a single dose of mRESVIA in study 1 received a revaccination dose at 24 months after primary vaccination with mRESVIA. In study 5 (n=506), participants ≥60 years of age previously vaccinated with another authorised RSV vaccine received mRESVIA at least 12 months after primary vaccination. Across studies, the overall safety and reactogenicity profile following revaccination was consistent with the established safety profile of mRESVIA.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

No cases of overdose have been reported.
Overdose with mRESVIA is unlikely due to its single dose presentation (see section “Posology”).
In case of overdose, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

Properties/Effects

ATC code

J07BX05

Mechanism of action

mRESVIA is an mRNA-based vaccine encoding the membrane-anchored RSV-A F glycoprotein stabilised in the prefusion conformation through changes to the amino acid sequence. The RSV-A prefusion glycoprotein is antigenically cross-reactive to the RSV-B prefusion glycoprotein. The

prefusion F glycoprotein is the target of 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.

Clinical efficacy mRESVIA

Study 1 – in individuals 60 years of age and older

Study 1 (EUDRA CT number 2021-005026-20) is a phase 2/3 randomised, observer-blind, placebo controlled, pivotal study conducted in 22 countries in Central and Latin America, Africa, Asia Pacific, North America and Europe. The study evaluated the safety and efficacy of a single dose of mRESVIA for the prevention of RSV-LRTD in adults ≥ 60 years with or without underlying medical conditions.

The primary efficacy analysis population (per-protocol efficacy set) included 35 088 participants who received either mRESVIA (n=17 572) or placebo (n=17 516). Among all participants, 50.9% were male, 63.5% were White,12.2% were Black or African American, 8.7% were Asian, and 34.6% were Hispanic or Latino.

The median age was 67 years (range: 60-96), with 63.5% aged 60-69, 30.9% aged 70-79 and 5.5% aged ≥ 80 years. A total of 6.9% had protocol-defined LRTD risk factors [congestive heart failure (CHF) and/or chronic obstructive pulmonary disease (COPD)] and 29.3% had one or more comorbidity of interest. A total of 21.8% scored “vulnerable” or “frail” according to Edmonton Frail Scale.

The primary efficacy endpoints were the prevention of a first episode of RSV-LRTD with ≥ 2 or ≥ 3 symptoms, occurring between 14 days and 12 months post injection. RSV-LRTD was defined as reverse transcription polymerase chain reaction (RT PCR) confirmed RSV infection and radiologic evidence of pneumonia or experienced new or worsening of ≥ 2 of predefined symptoms ≥24 hours including shortness of breath, cough and/or fever, wheezing, sputum production, tachypnoea, hypoxemia and pleuritic chest pain.

The primary efficacy endpoints were met (lower bound of the alpha-adjusted confidence interval [CI] of the vaccine efficacy [VE] was > 20%), including VE of 83.7% (95.88% CI: 66.0%, 92.2%) against RSV-LRTD as defined by ≥ 2 symptoms. The other primary efficacy endpoint against RSV-LRTD defined by ≥ 3 symptoms was also met, with a VE of 82.4% (96.36% CI: 34.8%, 95.3%). These analyses were performed after a median of 3.7 months of follow-up.

An additional analysis of efficacy was performed after a median of 8.6 months (range: 0.5 to 17.7 months) of follow-up. A single dose of mRESVIA met the same criterion as defined in the primary analysis for the prevention of RSV-LRTD with ≥ 2 symptoms (see Table 2). The vaccine efficacy

against RSV-LRTD with ≥ 3 symptoms was 63.0% (95% CI: 37.3%, 78.2%; number of participants in mRESVIA group was n=19 / N=18 112 and in the placebo group was n=51 / N=18 045).

At the time of the additional analysis, point estimates of VE in the subgroup analyses by age, comorbidity and frailty were generally consistent with VE of overall population based on the PPE Set (Table 2).

Table 2. Additional analysis of vaccine efficacy (VE) of mRESVIA to prevent first episode of RSV-LRTD (with 2 or more symptoms) 14 days post-injection up to 12 months post-injection by subgroups (per-protocol efficacy set)

Subgroup	mRESVIA Cases, n/N*	Placebo Cases, n/N*	VE, % (95% CI)
Overall	47/18 112	127/18 045	63.3 (48.7, 73.7)
Age group			
60 to 69 years	31/11 219	77/11 170	60.1 (39.5, 73.7)
70 to 79 years	10/5 464	45/5 439	78.0 (56.3, 88.9)
≥ 80 years	6/1 429	5/1 436	NA†
Comorbidities‡			
None (0)	31/12 751	76/12 796	59.5 (38.5, 73.4)
One or more (≥ 1)	16/5 361	51/5 249	69.3 (46.1, 82.5)
Frailty status			
Fit (0-3)	37/13 417	104/13 274	65.0 (49.0, 75.9)
Vulnerable/Frailty (≥ 4)	9/3 817	17/3 884	46.5 (-20.0, 76.2)

* Based on the number of participants in each subgroup.
† NA = 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.

As shortness of breath is associated with more severe RSV disease, an exploratory analysis was conducted. A total of 54 cases of RSV-LRTD with shortness of breath occurred: 43 in placebo recipients and 11 in mRESVIA recipients.

Efficacy against RSV-associated LRTD over up to 3 RSV seasons (median 24 months follow-up)

In participants 60 years of age and older, after a median of 24 months which includes exposure over up to three consecutive RSV seasons, VE against RSV-LRTD was 44.3% (95% CI 32.4, 54.1) with ≥2 symptoms and 50.8% (95% CI 33.2, 63.8) with ≥3 symptoms.

VE across subgroups defined by age, comorbidity, frailty, and RSV subtypes (RSV-A and RSV-B) were generally consistent with the overall population.

In an exploratory analysis of RSV-associated LRTD with shortness of breath associated with more severe disease, VE was 53.2% (95% CI: 32.4, 67.6) with 89 cases among placebo recipients and 42 cases among mRESVIA recipients.

Study 2 – in individuals 18 through 59 years
Study 2 is a phase 3 randomised, double-blind trial to evaluate the immunogenicity and safety of mRESVIA in individuals 18 through 59 years of age at increased risk for LRTD caused by RSV. The clinical study was conducted in the US, Canada and United Kingdom.

Eligible participants enrolled in the study had at least one of the conditions that increased their risk for developing RSV-LRTD. Of the 494 participants in the Per-Protocol (PP) Set, diabetes mellitus (DM) was reported in 59.7%, persistent asthma in 38.1%, coronary artery disease (CAD) in 20.9%, chronic obstructive pulmonary disease (COPD) in 10.1%, congestive heart failure (CHF) in 8.9%, and chronic respiratory disease other than COPD or asthma in approximately 2.4%. Additionally, 63.6% of participants had a BMI of 30 kg/m² or higher, indicating a significant prevalence of obesity within the study population.

The median age was 53 years (range: 19-59). Most participants were White (80.2%), 53.6% were female and 27.5% of participants were Hispanic or Latino.

Efficacy of mRESVIA in this population was inferred by comparison of RSV neutralising antibody (nAb) levels at Day 29 post-vaccination to those in a subset of Study 1 participants ≥ 60 years of age. Non-inferiority was demonstrated for the nAb geometric mean titres (GMTs) for RSV A and RSV B [Study 2 PP/Study 1 Per-Protocol Immunogenicity (PPI) subset; lower bound of the 2-sided 95% CI of the geometric mean ratio (GMR) > 0.667].

Table 3: Day 29 nAb GMT and GMR (nAb against RSV-A and RSV-B) from Study 2 (individuals 18 through 59 years of age at increased risk for LRTD caused by RSV) and Study 1 (individuals 60 years of age and older)

	mRESVIA Study 2 - (PP set) (N=494)			mRESVIA Study 1 - (PPI set) (N=1 515)			Study 2 versus Study 1	
nAb titre (IU/mL)	**N1**	**Model-based GMT[a]**	**95% CI**	**N1**	**Model-based GMT[a]**	**95% CI**	**Adjusted GMR**	**95% CI**
RSV-A	492	23 245	21 326, 25 336	1 513	19 988	19 038, 20 985	1.163	1.053, 1.285
RSV-B	489	7 831	7 242, 8 467	1 511	6 901	6 603, 7 213	1.135	1.037, 1.242

CI=confidence interval; GMT=geometric mean titre; GMR=geometric mean ratio; LRTD=lower respiratory tract disease; nAb=neutralising antibody; PP=Per-Protocol; PPI=Per-Protocol Immunogenicity; RSV-A=respiratory syncytial virus subtype A; RSV-B= respiratory syncytial virus subtype B.

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

[a] The model-based GMT is estimated on Analysis of covariance (ANCOVA) model.

Study 3 – in immunocompromised individuals 18 years of age and older

The single-arm, open-label Phase 3 study evaluated the safety, reactogenicity and immunogenicity of mRESVIA in 150 adult solid organ transplant (SOT) recipients (kidney, liver or lung transplants). This study was conducted in the United States, Canada and the United Kingdom.

Participants had undergone solid organ transplant at least 180 days prior to the day of consent and were receiving chronic immunosuppressive therapy for the prevention of allograft rejection at the time of enrolment. A second dose of mRESVIA was administered approximately 2 months (57 days) after the first dose.

A single dose of mRESVIA was immunogenic in SOT recipients. By Day 29, robust increases in nAb titres were observed for both RSV-A and RSV-B, with Geometric Mean Fold Rise (GMFRs) of 4.92 and 3.38, respectively. These responses were consistent across transplant types. Seroresponse Rate (SRRs) at Day 29 were 51.0% for RSV-A and 40.1% for RSV-B.

A second dose may provide additional benefit, particularly in some severely immunocompromised individuals. By Day 85, following the second dose of mRESVIA (50 mcg), GMTs rose further particularly in kidney and lung transplant recipients, with GMFRs reaching 7.07 for RSV-A and 5.17 for RSV-B. SRRs also increased by Day 85, to 64.5% for RSV-A and 56.3% for RSV-B. nAb responses persisted through Day 181, with GMFRs of 4.5 for RSV-A and 3.8 for RSV-B, and SRRs of 52.9% and 45.7%, respectively.

Studies 1B, 4C, and 5 – in Adults (revaccination)

Three phase 3 studies evaluated revaccination with mRESVIA administered after primary RSV vaccination. Study 4C (n=543) is a phase 3, single-arm, open-label study in participants ≥50 years of age previously vaccinated with mRESVIA, in which participants received a revaccination dose at 12 months after the primary vaccination with mRESVIA. In study 1B (n=998), participants previously vaccinated with mRESVIA in study 1 received a revaccination dose 24 months after the primary vaccination with mRESVIA. Study 5 (n=506) is an ongoing phase 3, single-arm, open-label study in participants ≥60 years of age, in which mRESVIA was administered at least 12 months after primary vaccination with another authorised RSV vaccine.

In studies 4C and 1B, prespecified non-inferiority criteria were met for nAb responses against RSV-A and RSV-B at Day 29 post-revaccination compared with primary vaccination. In study 5, at Day 29 nAb responses were evaluated in an exploratory post hoc analysis and were similar to those observed following primary vaccination. Revaccination with mRESVIA as early as 12 months after the primary dose resulted in immune responses comparable to those observed after the primary dose, including when administered after another authorised RSV vaccine.

RSV immune responses following vaccination with mRESVIA were consistent across demographic and clinical subgroups, including those with chronic medical conditions or increased BMI. Similar immune responses and vaccine effectiveness are expected in healthy adults aged 18 through 59 years of age.

Pharmacokinetics

Absorption

Not applicable.

Distribution

Not applicable.

Metabolism

Not applicable.

Elimination

Not applicable.

Kinetics in specific patient groups

Renal impairment

No clinical studies have been conducted to investigate the effect of renal impairment.

Hepatic impairment

No clinical studies have been conducted to investigate the effect of hepatic impairment.

Preclinical data

Non-clinical data reveal no special hazards for humans based on conventional studies of repeat toxicity, genotoxicity and developmental and reproductive toxicity.

General toxicity

General toxicity studies were conducted in rats (intramuscularly with mRESVIA receiving up to two doses that exceeded the human dose, once every 3 weeks or intramuscularly receiving up to 4 dose administrations of related vaccine drug products once every 2 weeks). Transient and reversible injection site oedema and erythema and transient and reversible changes in laboratory tests (including increases in eosinophils, activated partial thromboplastin time, and fibrinogen) were observed. Results suggests the toxicity potential to humans is low.

Genotoxicity/carcinogenicity

In vitro and in vivo genotoxicity studies were conducted to evaluate the novel lipid component SM 102 of the vaccine. Results suggests the genotoxicity potential to humans is very low. Carcinogenicity studies were not performed.

Developmental and reproductive toxicity

In a combined developmental and reproductive toxicity study, mRESVIA was administered to female rats 4 times intramuscularly at 96 micrograms/dose (twice prior to mating [28 and 14 days prior] and twice after mating [on gestation days 1 and 13]). Anti-RSV antibodies were present in maternal animals from prior to mating to the end of the study on lactation day 21, as well as in foetuses and offspring, and maternal milk. There were no vaccine-related adverse effects on female fertility, pregnancy, embryo foetal or offspring development or postnatal development.

Other information

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products or diluted.

Shelf life

Do not use this medicine after the expiry date ("EXP") stated on the pack.

Special precautions for storage

Store in a freezer between -40°C to -15°C.
Keep the pre-filled syringes in the original carton in order to protect from light.

Keep out of the reach of children.

Storage conditions after thawing

Within the shelf life of 1 year, stability data indicate that the vaccine is stable for 30 days when stored at 2 °C to 8 °C and protected from light. At the end of 30 days, the vaccine should be used immediately or discarded.
Once thawed, the vaccine should not be refrozen.
Upon moving the vaccine to 2 °C to 8 °C storage, the outer carton should be marked with the new expiry date at 2 °C to 8 °C.
If the vaccine is received at 2 °C to 8 °C, it should then be stored at 2 °C to 8 °C. The use by date corresponding to these storage conditions would be marked on a label on the carton. Please note in that case the expiration date (“EXP”) printed on the outer carton and on the pre-filled syringe for storage between -40°C to -15°C is not pasted over.
The pre-filled syringes may be stored at 8 °C to 25 °C for up to 24 hours after removal from refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Do not refrigerate after being stored at 8 °C to 25 °C. Discard the syringe if not used within this time.
Transportation of thawed pre-filled syringes in the outer carton in liquid state at 2 °C to 8 °C
If transport at -40 °C to -15 °C is not feasible, available data support transportation of one or more thawed pre-filled syringes in liquid state at 2 °C to 8 °C (within the 30 days shelf life).
Once thawed and transported in liquid state at 2 °C to 8 °C, pre-filled syringes should not be refrozen and should be stored at 2 °C to 8 °C until use.

Instructions for handling

This medicinal product should be administered by a trained healthcare professional using aseptic techniques to ensure sterility.
Handling instructions for mRESVIA before use
The vaccine is ready to use once thawed.
Do not dilute the product.
Do not shake the pre-filled syringe before use.
The pre-filled syringe is for single use only.
Do not use if the pre-filled syringe has been dropped or damaged or the security seal on the carton has been broken.

mRESVIA is shipped and supplied either as a frozen or thawed pre-filled syringe (see section “Special Precautions for storage”). If the vaccine is frozen, it must be completely thawed before use. Thaw each pre-filled syringe before use, either in the refrigerator or at room temperature, following the instructions in Table 4.

Prior to immediate use, single blisters or pre-filled syringes may be removed from a carton of 1 or 10 pre-filled syringes and thawed either in the refrigerator or at room temperature. The remaining blisters or syringes must continue to be stored in their original carton in the freezer or refrigerator.

Table 4. Thawing conditions and times based on pack size and temperature before use

Pack size	Thaw instructions and durations				
	Thaw temperature (in refrigerator)	**Thaw duration**		**Thaw temperature (at room temperature)**	**Thaw duration**
1 pre-filled syringe in carton	2 °C to 8 °C	100 min	**or**	15 °C to 25 °C	40 min
10 pre-filled syringes in carton	2 °C to 8 °C	160 min		15 °C to 25 °C	80 min
1 pre-filled syringe (removed from carton)	2 °C to 8 °C	100 min		15 °C to 25 °C	40 min

- After thawing, the vaccine cannot be refrozen.
- If the vaccine has been thawed, the pre-filled syringe is ready to administer. Syringes should not be returned to the refrigerator after thawed at room temperature.
- The pre-filled syringes may be stored at 8 °C to 25 °C for a total of 24 hours after removal from refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Discard the syringe if not used within this time.

Administration

- Remove a pre-filled syringe from the blister or tray.
- The vaccine should be inspected visually for particulate matter and discolouration prior to administration. mRESVIA is a white to off-white dispersion. Do not administer if vaccine is discoloured or contains other particulate matter.
- 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.
- The vaccine should be administered immediately after uncapping.
- Canulas are not provided in the pack.
- Use a sterile canula of the appropriate size for intramuscular injection (21 gauge or thinner canulas).

- Attach the canula by twisting in a clockwise direction until the canula fits securely on the pre filled syringe.
- Administer the entire dose intramuscularly.
- Discard the pre-filled syringe after use.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Authorisation number

69995 (Swissmedic) mRESVIA dispersion for injection in pre-filled syringe

Packs

Pack-sizes:

1 pre-filled syringe per carton. The pre-filled syringe contains one dose of 0.5 ml [B].

10 pre-filled syringes per carton. Each pre-filled syringe contains one dose of 0.5 ml [B].

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

Marketing authorisation holder

Moderna Switzerland GmbH, Basel

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