swissmedic

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Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report
Extension of therapeutic indication

Arexvy

International non-proprietary name:	respiratory syncytial virus (RSV) prefusion F protein
Pharmaceutical form:	powder and suspension for suspension for injection
Dosage strength(s):	120 micrograms / 0.5 mL
Route(s) of administration:	intramuscular
Marketing authorisation holder:	GlaxoSmithKline AG
Marketing authorisation no.:	69310
Decision and decision date:	extension of therapeutic indication approved on 15 April 2025

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
LRTI	Lower respiratory tract infection
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
RSV	Respiratory syncytial virus
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)

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

2.2 Indication and dosage

2.2.1 Requested indication

Arexvy is indicated for active immunisation to prevent lower respiratory tract disease caused by respiratory syncytial virus (RSV) in:
- adults 60 years of age and older
- adults 50 to 59 years of age at an increased risk of RSV disease.

Official vaccination recommendations should be considered.

2.2.2 Approved indication

Arexvy is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in:
- adults 60 years of age and older;
- adults 50 to 59 years of age who are at increased risk of RSV disease.

The official vaccination recommendations on the appropriate use should be observed.

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	30 August 2024
Preliminary decision	15 January 2025
Response to preliminary decision	6 March 2025
Final decision	15 April 2025
Decision	approval

3 Medical context

Respiratory syncytial virus (RSV) is a single-stranded, negative-sense ribonucleic acid virus and a member of the *Pneumoviridae* family. RSV causes acute respiratory tract illness in persons of all ages. Two subtypes, A and B, are simultaneously present in most outbreaks, with A subtypes typically causing more severe disease. Clinical manifestation varies with age and health status. RSV typically causes seasonal outbreaks throughout the world. In the northern hemisphere, these usually occur from October or November to April or May, with a peak in January or February.

Healthy adults are infected with RSV repeatedly throughout their lives and typically have symptoms restricted to the upper respiratory tract. RSV is an important and often unrecognised cause of lower respiratory tract infection (LRTI) in older adults and immunocompromised adults, and an important cause of death in adults older than 50 years. Hospitalisation for RSV infection in adults may be complicated by cardiovascular events (e.g. worsening heart failure, acute coronary syndrome, arrhythmia).
Although virtually all individuals have been infected with RSV by the age of 2 years, previous infection with RSV does not appear to protect against reinfection, even in patients with high titres of specific antibody. Several observations suggest that humoral immunity is more important in ameliorating the severity of RSV infection than in preventing disease. Although individuals can be infected with RSV more than once, subsequent infections usually are milder, whether they occur in the same season or in different years.

For most adults, RSV treatment is supportive. While the optimal approach is uncertain, treatment in immunocompromised patients usually consists of a combination therapy with aerosolised or oral ribavirin in association with intravenous immune globulins.

In Switzerland, 2 RSV vaccines are currently approved. At the time of assessment, no vaccine was available for active immunisation of individuals younger than 60 years of age.

4 Nonclinical aspects

The applicant submitted a developmental and reproductive toxicity study in rabbits to support the extension of the indication for Arexvy to adults 50-59 years of age who are at increased risk of RSV disease.
The assessment report of the EU medical agency was considered.
No RSVPreF3/AS01E effects on female fertility or embryo-fetal, prenatal, and postnatal development were observed. No justification for the absence of ERA studies was submitted. This is acceptable considering the nature of the product and is in line with the valid EMA guidelines.
From the nonclinical point of view, there are no objections to approval of the proposed extension of indication.

5 Clinical aspects

The evaluation of the clinical data of this application for an extension of the indication to include adults aged 50 to 59 years at increased risk of RSV disease has been carried out in reliance on previous regulatory decisions by the EMA and FDA. The available assessment report of the EMA (Procedure No. EMEA/H/C/006054/II/0008) and the product information from these authorities were used as a basis for the clinical evaluation.

For further details concerning clinical pharmacology, dosing recommendations, efficacy, and safety, see section 7.1 of this report

6 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.

7 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for Arexvy 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.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.

Arexvy

Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)

Composition

Active substances

Respiratory syncytial virus (RSV) pre-fusion protein F (RSVPreF3 antigen), produced by recombinant DNA technology in Chinese Hamster Ovary (CHO) cells.

Excipients

*Powder (*RSVPreF3 antigen*):* trehalose dihydrate, polysorbate 80, potassium dihydrogen phosphate, dipotassium phosphate.
Suspension (*$AS01_E$ adjuvant):* purified *Quillaja* saponin (QS-21), 3-*O*-desacyl-4'-monophosphoryl lipid A (MPL), dioleoyl phosphatidylcholine, cholesterol, sodium chloride, disodium phosphate anhydrous, potassium dihydrogen phosphate, water for injections.
After reconstitution, one vaccine dose contains 1.78 mg sodium and 0.35 mg potassium.

Pharmaceutical form and active substance quantity per unit

Powder and suspension for suspension for injection (i.m.).
After reconstitution, 1 dose (0.5 mL) contains 120 micrograms of RSVPreF3[1] antigen adjuvanted with $AS01_E$[2].
[1] Respiratory syncytial virus (RSV) glycoprotein F stabilized in the pre-fusion conformation (RSVPreF3) produced by recombinant DNA technology in Chinese Hamster Ovary (CHO) cells.
[2] The $AS01_E$ Adjuvant System is composed of the plant extract *Quillaja saponaria* Molina, fraction 21 (QS-21) (25 micrograms) and 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota* (25 micrograms).
The powder is white.
The suspension is an opalescent, colourless to pale brownish liquid.

Indications/Uses

Arexvy is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD)

caused by respiratory syncytial virus in:

- adults 60 years of age and older;
- adults 50 through 59 years of age who are at increased risk for RSV disease.

The official vaccination recommendations on the appropriate use should be observed.

Dosage/Administration

Consideration should be given to official vaccination recommendations for the immunisation schedules.
To ensure traceability of biotechnological medicinal products, it is recommended that the trade name and batch number be documented for each treatment.

Usual dosage

Arexvy is administered as a single dose of 0.5 mL.
The need for revaccination has not been established.
Children and adolescents
The safety and efficacy of Arexvy in children and adolescents younger than 18 years of age have not been established. No data is available. Arexvy is not authorised for use in the paediatric population.

Mode of administration

Arexvy is intended for intramuscular injection only, preferably in the deltoid muscle.
For instructions on reconstitution of the medicinal product before administration, see “Instructions for handling” section.

Contraindications

Hypersensitivity to the active substances or to any component of the vaccine (see “Composition” and “Pharmaceutical form and active substance quantity per unit”).

Warnings and precautions

Prior to immunisation
As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.
As with other vaccines, vaccination with Arexvy 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.
As with any vaccine, a protective immune response may not be elicited in all vaccinees.
Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

Precautions for use

Do not administer the vaccine intravascularly or intradermally. No data are available on subcutaneous administration of Arexvy.

As with other vaccines administered intramuscularly, Arexvy should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these individuals.

Systemic immunosuppressive medications and immunodeficiency

Safety and immunogenicity data on Arexvy are not available for immunocompromised individuals. Patients receiving immunosuppressive treatment or patients with immunodeficiency may have a reduced immune response to Arexvy.

Limitations of the clinical data

Studies on the clinical efficacy and safety of Arexvy have been conducted in adults 60 years of age and older.

The effectiveness of Arexvy in adults between 50 and 59 years of age at an increased risk for RSV disease can be inferred on the basis of an immune response comparable to that in adults 60 years of age and older, for whom the efficacy of the vaccine has been proven.

Excipients

This medicinal product contains less than 1 mmol of sodium (23 mg) per vaccine dose, i.e. it is almost “sodium-free”.

This medicinal product contains potassium, but less than 1 mmol (39 mg) per vaccine dose, i.e. it is almost “potassium-free”.

Interactions

Use with other vaccines

Arexvy can be administered concomitantly with inactivated seasonal influenza vaccines (standard-dose unadjuvanted, high-dose unadjuvanted, or standard-dose adjuvanted).

The safety profile of Arexvy when co-administered with inactivated seasonal influenza vaccines was comparable to when Arexvy was administered alone.

In three open-label Phase III clinical studies, the participants were randomised and received 1 dose of Arexvy either concomitantly on Day 1 or separately (1 month later) with an inactivated seasonal quadrivalent influenza vaccine (standard-dose unadjuvanted, adults ≥60 years of age; high-dose unadjuvanted, adults ≥65 years of age; or standard-dose adjuvanted, adults ≥65 years of age).

In the case of concomitant administration of Arexvy with a standard-dose adjuvanted seasonal influenza vaccine, there were no indications of any clinically relevant impairment of the immune response to RSV-A or any of the four influenza antigens. The immune response triggered by flu A/H3N2 did not, however, meet the predefined criteria for non-inferiority (the upper limit (UL) of the 95% CI for the GMT ratio was 1.53, so was above the predefined limit of ≤1.5).

The RSV-B neutralisation titres were comparable across all three studies for both separate and concomitant administration.
In the case of concomitant administration of Arexvy and seasonal inactivated influenza vaccines, numerically lower RSV-A and RSV-B neutralising antibody titres and numerically lower influenza A and B haemagglutination inhibition antibody titres were observed compared with separate administration. However, this was not observed consistently across all studies. The clinical relevance of these observations is not known.
If Arexvy is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.
Currently, there are no available data on the concomitant administration of Arexvy with other vaccine.

Pregnancy, lactation

Pregnancy

There are no data on the use of Arexvy in pregnant women. The administration of Arexvy during pregnancy is not recommended.
After administration of an investigational unadjuvanted RSVPreF3 vaccine to 3,557 pregnant women in a single clinical trial, an increase in preterm births was observed compared to placebo.
Results from animal studies with an investigational unadjuvanted RSVPreF3 vaccine and results with Arexvy do not indicate direct or indirect reproductive toxicity (see “Preclinical data”).

Lactation

To date, there are no data on the excretion of Arexvy in human or animal milk. Arexvy is not recommended in breast-feeding women.

Fertility

There are no data on the effects of Arexvy on human fertility.
Animal studies do not indicate any direct or indirect harmful effects on female fertility.

Effects on ability to drive and use machines

No studies on the effects of Arexvy on the ability to drive and use machines have been performed.

Undesirable effects

The safety profile presented below is based on a placebo-controlled Phase III clinical study (conducted in Europe, North America, Asia and the Southern Hemisphere) in adults ≥60 years of age in which 12,467 adults received one dose of Arexvy and 12,499 received placebo with a follow-up period of approximately 12 months.

Adverse drug reactions are listed below by MedDRA system organ class and by frequency according to the following convention: “very common” (≥1/10), “common” (≥1/100, <1/10), “uncommon” (≥1/1,000, <1/100), “rare” (≥1/10,000, <1/1,000), “very rare” (<1/10,000).

System Organ Class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Uncommon	lymphadenopathy
Immune system disorders	Uncommon	hypersensitivity reactions (such as rash)
Nervous system disorders	Very common	headache (27.2%)
Respiratory, thoracic, and mediastinal disorders	Common	rhinorrhea
Gastrointestinal disorders	Uncommon	nausea, abdominal pain
Musculoskeletal and connective tissue disorders	Very common	myalgia (28.9%), arthralgia (18.1%)
General disorders and administration site conditions	Very common	injection site pain (60.9%), fatigue (33.6%)
	Common	injection site erythema, injection site swelling, fever, chills
	Uncommon	injection site pruritus
		pain, malaise

In Study RSV OA=ADJ-006 (NCT04886596), within 30 days of vaccination, atrial fibrillation was reported in 10 subjects who received Arexvy and 4 subjects who received placebo (of which 7 events in the Arexvy arm and 1 event in the placebo arm were serious); the onset of symptoms ranged from 1 to 30 days post-vaccination. The information currently available on the atrial fibrillation is insufficient to determine a causal relationship to the vaccine. Within 6 months of vaccination, serious events of atrial fibrillation were reported in 13 subjects who received Arexvy and 15 subjects who received placebo.

Serious Adverse Events Reported from Other Studies

Study RSV OA=ADJ-004 (NCT04732871): One case of Guillain-Barré syndrome beginning 9 days after Arexvy vaccination was reported in one participant enrolled at a study site in Japan.

Additionally, in a placebo-controlled Phase III clinical study, 769 participants between 50 and 59 years of age (including 386 participants with pre-defined, stable, chronic medical conditions leading to an increased risk for RSV disease) and 381 participants 60 years of age and older received one dose of Arexvy. The reported adverse reactions were consistent with those presented in the table above. There was a higher incidence of injection site pain (76%), fatigue (40%), myalgia (36%), headache (32%) and arthralgia (23%), in participants between 50 and 59 years of age compared with those 60 years of age

and older in the study. However, the duration and severity of these events were comparable across age groups in the study.

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

Insufficient data are available.

Properties/Effects

ATC code

J07BX05

Mechanism of action

Arexvy induces the functional humoral immune responses against the RSV-A and RSV-B subtypes and the antigen-specific cellular immune responses which contribute to protect against RSV-associated LRTD.
Non-clinical data show that $AS01_E$ induces a local and transient activation of the innate immune system through specific molecular pathways. The adjuvant effect of $AS01_E$ is the result of interactions between MPL and QS-21 formulated in liposomes. This facilitates the recruitment and activation of antigen-presenting cells carrying vaccine-derived antigens in the draining lymph node, which in turn leads to the generation of RSVPreF3-specific CD4+ T cells and induction of RSV-A- and RSV-B-neutralizing antibody responses. In addition, RSVPreF3 formulated with $AS01_E$ can elicit specific binding antibodies directed to site Ø, a highly neutralizing sensitive epitope, exposed only on the pre-fusion conformation of the F protein.

Pharmacodynamics

1. Efficacy of Arexvy

Efficacy of Arexvy against RSV-associated LRTD in adults 60 years and older was evaluated in an ongoing, Phase III, randomised, placebo-controlled, observer-blind clinical study (RSV OA=ADJ-006) conducted in 17 countries from the Northern and Southern Hemispheres. Participants are planned to be followed for up to 36 months.
The primary population for the efficacy analysis (referred to as the modified Exposed Set, included adults 60 years of age and older who received at least 1 dose of Arexvy or placebo and who did not report an RSV-confirmed acute respiratory illness (ARI) prior to Day 15 after vaccination) included

24,960 participants randomised equally to receive 1 dose of Arexvy (N = 12,466) or placebo (N = 12,494). At the time of the primary efficacy analysis, participants had been followed for the development of RSV-associated LRTD for up to 10 months (median of 6.7 months).

At baseline, 39.3% of participants had at least one comorbidity of interest; 19.7% of participants had an underlying cardiorespiratory condition (COPD, asthma, any chronic respiratory/pulmonary disease, or chronic heart failure) and 25.8% of participants had endocrinometabolic conditions (diabetes, advanced liver or renal disease).

Using the Gait speed test, 38.3% of participants were ranked as pre-frail (0.4-0.99m/s walking speed) and 1.5% as frail (<0.4 m/s walking speed or who were not able to perform the test).

Efficacy against RSV-associated LRTD over the first RSV season

The primary objective was to demonstrate the efficacy of Arexvy in the prevention of a first episode of confirmed RSV-A and/or RSV-B associated LRTD during the first season. Confirmed RSV cases were determined by quantitative Reverse Transcription Polymerase Chain Reaction (qRT-PCR) on nasopharyngeal swab. LRTD was defined based on the following criteria: the participant must have experienced at least 2 lower respiratory symptoms/signs including at least 1 lower respiratory sign for at least 24 hours, or experienced at least 3 lower respiratory symptoms for at least 24 hours. Lower respiratory symptoms included: new or increased sputum, new or increased cough, new or increased dyspnea (shortness of breath). Lower respiratory signs included: new or increased wheezing, crackles/ronchi, respiratory rate ≥ 20 respirations/min, low or decreased oxygen saturation (O_2 saturation <95% or ≤90 % if baseline is <95%) or need for oxygen supplementation.

Compared with placebo, Arexvy significantly reduced the risk of developing RSV-associated LRTD by 82.6% (96.95% CI: [57.9, 94.1]) in participants 60 years of age and older, which met the pre-specified success criterion for the primary study objective (Table 1). Vaccine efficacy against RSV-LRTD is observed through the median follow-up period of 6.7 months.

The vaccine efficacy against RSV A-associated LRTD cases and RSV B-associated LRTD cases was 84.6% (95% CI [32.1, 98.3]) and 80.9% (95% CI [49.4, 94.3]), respectively.

Table 1: Efficacy Analysis over the first RSV season: First RSV-associated LRTD Overall, by Age and co-morbidity subgroups in RSV OA=ADJ-006 (modified Exposed Set)

Subgroup	Arexvy			Placebo			
	N	n	Incidence rate per 1,000 person-years	N	n	Incidence rate per 1,000 person-years	% Efficacy (CI)[a]
Overall (≥ 60 years)[b]	12466	7	1.0	12494	40	5.8	82.6 (57.9, 94.1)
60-69 years	6963	4	1.0	6979	21	5.5	81.0 (43.6, 95.3)
70-79 years	4487	1	0.4	4487	16	6.5	93.8 (60.2, 99.9)

Participants with at least 1 comorbidity of interest	4937	1	0.4	4861	18	6.6	94.6 (65.9, 99.9)

[a]CI = Confidence Interval (96.95% for the overall (≥ 60 years) and 95% for all subgroup analyses). Two-sided exact CI for vaccine efficacy is derived based on Poisson model adjusted by age categories and regions.

[b]Primary confirmatory objective with pre-specified success criterion of lower limit of the 2-sided CI for vaccine efficacy above 20%

N = Number of participants included in each group

n = Number of participants having first occurrence of RSV-confirmed LRTD occurring from Day 15 post vaccination

Compared with placebo, Arexvy significantly reduced the risk of developing RSV-associated LRTD by 84.4% (95% CI: [46.9, 97.0]) in participants 70 years of age and older. The vaccine efficacy in the subgroup of participants 80 years of age and older (1016 participants in Arexvy vs 1028 participants in placebo) cannot be conclusively assessed due to the low number of total cases accrued (5 cases).

Compared with placebo, Arexvy significantly reduced the risk of developing RSV-associated LRTD in pre-frail participants by 92.9% (95% CI [53.4, 99.8]). The vaccine efficacy in the frail subgroup (189 participants in Arexvy vs 177 participants in placebo) cannot be conclusively assessed due to the low number of total cases accrued (2 cases).

Amongst 18 RSV-LRTD cases with at least 2 lower respiratory signs or preventing everyday activities, 4 cases of severe RSV-LRTD requiring oxygen supplementation occurred in the placebo group, while there were none in the RSVPreF3 group.

Efficacy against RSV-associated LRTD over 2 RSV seasons

Over 2 RSV seasons (up to the end of the second season in the Northern Hemisphere), with a median follow-up time of 17.8 months, the vaccine efficacy against RSV-associated LRTD was 67.2% (97.5% CI [48.2, 80.0]) in participants 60 years of age and older.

Subgroup analyses of RSV-associated LRTD vaccine efficacy showed similar efficacy point estimates.

Table 2: Efficacy Analyses over two RSV seasons: First RSV-associated LRTD Overall, by Age and co-morbidity subgroups in RSV OA=ADJ-006 (modified Exposed Set)

Subgroup	Arexvy[a]			Placebo			% Efficacy[c] (CI)[d]
	N[b]	n	Incidence rate per 1,000 person-years	N[b]	n	Incidence rate per 1,000 person-years	
Over 2 RSV seasons							
Overall (≥ 60 years)	12469	30	2.0	12498	139	8.0	67.2 (48.2, 80.0)

60 to 69 years	6963	17	2.1	6981	74	7.7	65.4 (40.4, 80.9)
70 to 79 years	4489	9	1.7	4489	55	8.8	74.9 (48.4, 89.2)
Participants with at least 1 comorbidity of interest	4983	16	2.7	4919	72	10.6	66.7 (41.8, 82.0)

[a]Participants who received a second dose of Arexvy did not contribute to these efficacy analyses after receipt of Dose 2.

[b]Several analyses were performed resulting in a different number of participants included in each analysis due to new or updated information obtained for some participants

[c]VE(%) Poisson method – adjusted by age, region, and season for the overall analysis (≥ 60 years) and participants with at least 1 comorbidity of interest and adjusted by region and season for the analysis by age category.

[d]CI = Confidence Interval (97.5% for the overall ≥60 years and 95% for all subgroup analyses).

Two-sided exact CI for vaccine efficacy is derived based on Poisson model adjusted by age categories, regions and season.

N = Number of participants included in each group.

n = Number of participants having first occurrence of RSV-confirmed LRTD occurring from Day 15 post-vaccination.

The vaccine efficacy against RSV-associated LRTD was 69.3% (95% CI [43.4, 84.6]) in participants 70 years of age and older. The vaccine efficacy in the subgroup of participants 80 years of age and older cannot be conclusively assessed due to the low number of total cases accrued (4 cases in the Arexvy group and 10 cases in the placebo group).

The vaccine efficacy against severe RSV-associated LRTD was 78.8% (95% CI [52.6, 92.0]) in participants 60 years of age and older (7 cases in the Arexvy group and 48 cases in the placebo group, amongst which 1 case in the Arexvy group and 5 cases in the placebo group required supportive therapy).

In the study RSV OA=ADJ-006, the vaccine efficacy against RSV-associated LRTD over the second RSV season a with median follow-up of 6.3 months was 56.1% (95% CI [28.2, 74.4]) in participants 60 years of age and older (20 cases in the Arexvy group and 91 cases in the placebo group).

2. Immunogenicity of Arexvy

An immunological correlate of protection has not been established; therefore, the level of immune response that provides protection against RSV-associated LRTD is unknown.

Adults 60 years of age and over

The immune responses to Arexvy were evaluated in Phase III immunogenicity and safety study RSV OA=ADJ-004 in adults 60 years of age and older. Functional humoral immune responses post-vaccination compared to pre-vaccination were evaluated with results from 940 participants for RSV-A and 941 participants for RSV-B for month 1 vs. pre-vaccination, and 928 participants for RSV-A and 929 participants for RSV-B at month 6 vs. pre-vaccination. The cell-mediated immune responses were evaluated with results from 471 participants at pre-vaccination, 410 at month 1 and 440 at month 6.
Arexvy elicited RSV-specific humoral and cellular immune responses. The geometric mean increase of the RSV-A and RSV-B neutralizing titers compared to pre-vaccination were 10.5-fold (95% CI [9.9, 11.2]) and 7.8-fold (95% CI [7.4, 8.3]) at 1-month post-vaccination, respectively, and 4.4-fold (95% CI [4.2, 4.6]) and 3.5-fold (95% CI [3.4, 3.7]) at 6-months post-vaccination, respectively. The median frequency (percentile [25^{th}, 75^{th}]) of the RSVPreF3-specific CD4+ T-cells (per million of CD4+ T cells) was 1339.0 (829.0, 2136.0) 1-month post-vaccination and 666.0 (428.0, 1049.5) 6-months post-vaccination as compared to 191.0 (71.0, 365.0) pre-vaccination.

Adults 50 through 59 years of age at increased risk for RSV disease

The non-inferiority of the immune response to Arexvy in adults 50 through 59 years of age compared to adults 60 years of age and older, for whom the vaccine efficacy against RSV-associated LRTD was demonstrated, was evaluated in an observer-blind, randomised, placebo-controlled Phase III study (RSV OA=ADJ-018).
Cohort 1 consisted of participants 50 through 59 years of age separated in 2 sub-cohorts according to their medical history. Sub-cohort 1 consisted of participants with pre-defined, stable, chronic medical conditions leading to an increased risk for RSV disease (Arexvy, N=386; placebo, N=191) such as chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney or liver disease. Sub-cohort 2 consisted of participants without pre-defined, stable, chronic medical conditions (Arexvy, N=383; placebo, N=192). Cohort 2 consisted of participants 60 years of age and older (Arexvy, N=381).
The primary immunogenicity objective was to demonstrate non-inferiority of the humoral immune response (in terms of RSV-A and RSV-B neutralizing titers) following the administration of Arexvy at 1-month post-vaccination in participants 50-59 years of age with pre-defined, stable, chronic medical conditions leading to an increased risk for RSV disease, compared to participants 60 years of age and older.

Table 3: Summary of adjusted geometric mean titer ratios and the differences in the seroresponse rate in terms of RSV-A- and RSV-B-neutralizing titres (ED60) in adults 60 years of age and older (OA) compared with adults between 50 and 59 years of age with predefined, stable, chronic medical conditions[a] associated with an increased risk for RSV disease (Adults-AIR) - Per Protocol Set.

RSV-A-neutralizing antibody titers (ED60)

	Adjusted GMT (95% CI)	Adjusted GMT ratio (95% CI)[b]	SRR (%) (95% CI)	SRR difference (95% CI)[c]
OA	7440.1 (6768.4; 8178.5)	0.8 (0.7; 1.0)	80.4 (75.8; 84.5)	-6.5 (-12.1; -0.9)
Adults-AIR	8922.7 (8118.2; 9806.9)		86.9 (82.8; 90.3)	
RSV-B-neutralizing antibody titers (ED60)				
	Adjusted GMT (95% CI)	**Adjusted GMT ratio (95% CI)[b]**	**SRR (95% CI)**	**SRR difference (95% CI)[c]**
OA	8062.8 (7395.9; 8789.9)	0.8 (0.7; 0.9)	74.5 (69.5; 79.0)	-7.2 (-13.3; -0.9)
Adults-AIR	10,054.7 (9225.4; 10,958.7)		81.6 (77.1; 85.6)	

[a] Predefined, stable, chronic medical conditions such as chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney or liver disease.

[b,c] The predefined criteria for non-inferiority of immune responses were defined as the two-sided 95% CI upper limits for the adjusted GMT ratios (OA over Adults-AIR) ≤1.5 and the upper limits for the two-sided 95% CI for the SRR difference (OA minus Adults-AIR) ≤10% for participants 60 years of age and older (OA) compared with participants between 50 and 59 years of age with predefined, stable, chronic medical conditions associated with an increased risk for RSV disease (Adults-AIR).

ED60: estimated dilution 60; CI = confidence interval; GMT = geometric mean titer; SRR = seroresponse rate

The non-inferiority criteria of the immune responses for the RSV-A and RSV-B neutralizing titers were met. The efficacy of Arexvy in adults between 50 and 59 years of age at increased risk for RSV disease can be inferred from a comparison of the immune response in adults between 50 and 59 years of age with the immune response in adults 60 years of age and older for whom the vaccine efficacy was demonstrated.

Clinical efficacy

See under “Pharmacodynamics”.

Pharmacokinetics

Evaluation of pharmacokinetic properties is not required for vaccines.

Absorption

Not applicable.

Distribution

Not applicable.

Metabolism

Not applicable.

Elimination

Not applicable.

Preclinical data

Non-clinical data reveal no special hazards for humans based on general safety studies.
Reproductive and developmental studies with an unadjuvanted RSVPreF3 vaccine as well as results from a study with Arexvy in rabbits did not reveal any vaccine-related effects on female fertility, gestation, or embryo-foetal or offspring development.

Other information

Incompatibilities

This medicinal product must not be mixed with other medicinal products.

Shelf life

Do not use this medicine after the expiry date ("EXP") stated on the pack.
For shelf life after reconstitution of the medicinal product, see “Instructions for handling” section.

Special precautions for storage

Store in the refrigerator (2-8°C) in the original packaging to protect from light and keep out of the reach of children. Do not freeze. Discard if the vial has been frozen.
For storage conditions after reconstitution of the medicinal product, see “Instructions for handling” section.

Instructions for handling

The powder and suspension should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not reconstitute the vaccine.

How to prepare Arexvy:

Arexvy must be reconstituted prior to administration.

1. Withdraw the entire contents of the vial containing the suspension into a syringe.
2. Add the entire contents of the syringe into the vial containing the powder.
3. Gently swirl until the powder is completely dissolved.

The reconstituted vaccine is an opalescent, colourless to pale brownish liquid.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not administer the vaccine.
After reconstitution, the vaccine should be used promptly; if this is not possible, the vaccine should be stored in the refrigerator (2-8°C) or at room temperature up to 25°C. If the vaccine is not used within 4 hours, it should be discarded.
Before administration:
1. Withdraw 0.5 mL of the reconstituted vaccine into the syringe.
2. Change the needle so that you are using a new needle.
Administer the vaccine intramuscularly.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Authorisation number

69310 (Swissmedic)

Packs

1 vial with powder and 1 vial with suspension (B)

Marketing authorisation holder

GlaxoSmithKline AG, 3053 Münchenbuchsee

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