AREXVY

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IB /	Outcome:	18/08/2026		SmPC	

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000355568	This was an application for a group of variations. Q.I.d.1.a) Re-test period/storage period - Q.I.d.1.a.5 Extension of a re-test period/storage period supported by real time data fully in line with the stability protocol - Accepted Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.5 Extension of the shelf life of the finished product based on extrapolation of stability data in accordance with relevant stability guidelines - Accepted Q.II.f.1 Change in the shelf life or storage - Q.II.f.1.z Other variation - Accepted				
Variation type IB / EMA/VR/0000327332	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Q.II.c.2 Change in analytical procedure for an excipient - Q.II.c.2.z Other variation - Accepted	18/06/2026			

Variation type IB / EMA/VR/0000304496	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Q.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Q.II.b.3.z Other variation - Accepted	21/05/2026			
Variation type II / EMA/VR/0000309343	Outcome: This was an application for a group of variations. B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.a Change that affects the product information - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Reduction in the testing	16/04/2026		SmPC, Labelling and PL	The SmPC, Annex A and the Package Leaflet have been updated by addition of information related to new presentations powder and suspension for suspension for injection in pre-filled syringe (vial/pre-filled syringe (EU/1/23/1740/003 and EU/1/23/1740/004).

	frequency of an analysis, from routine testing to skip or periodic testing (microbial testing of finished product). - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.2 Sterile medicinal products and biological/ immunological medicinal products - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.c The product is a biological/immunological medicinal product and the change requires an assessment of comparability - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.c Site where any manufacturing operation(s) take place,				

	except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted B.II.a) Description and composition - B.II.a.5 Change in concentration of a single-dose, total use parenteral product, where the amount of active substance per unit dose (i.e. the strength) remains the same - Accepted B.II.a.3.b Other excipients - B.II.a.3.b.3 Change that relates to a biological/immunological product - Accepted				
Variation type II / EMA/VR/0000301721	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update information on safety and immunogenicity data in immunocompromised (IC) adults ≥18 years of age receiving 1 or 2 doses of RSVPreF3 OA vaccine, based on final results from study RSV OA=ADJ-023 (219900); this is a Phase 2b, randomized, controlled, open-label	19/02/2026		SmPC and PL	SmPC new text The results from study ADJ-023 indicate that Arexvy is immunogenic in solid organ transplant (SOT) recipients. A single dose generated an immune response that was substantial, though lower compared to the immune response generated in healthy adults 50 years of age or older. However, based on the fact that the immune response was higher compared to the immune response seen after 1 year in the healthy adult group, substantial efficacy can be inferred, as the estimated VE in a second season of RSV was >55% after a single dose of Arexvy. A second dose further increased the immune response in SOT recipients. This increased response after a second dose was driven by SOT recipients receiving mycophenolate as part of their immunosuppressive regimen. Although the clinical

	study to evaluate the immune response and safety of the RSVPreF3 OA investigational vaccine in adults (≥18 years of age) when administered to lung and renal transplant recipients comparing 1 versus 2 doses and compared to healthy controls (≥50 years of age) receiving 1 dose. In addition, the MAH took the opportunity to introduce a minor editorial change to the PI.				relevance of the slight increase in GMTs, with overlapping confidential intervals (Cis), is unclear, it cannot be ruled out that the vulnerable population of immunocompromised subjects could benefit even from a slight increase in RSV neutralising antibodies. Therefore, the information provided is considered highly relevant for prescribers in order to enable a clinical judgement whether they consider a second dose warranted for an individual patient.
Variation type II / EMA/VR/0000276225	Outcome: C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted Extension of indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 18 years of age and older for AREXVY, based on results from study 222253 (RSV OA=ADJ-025); this is a Phase 3b, open-label study to evaluate the non-inferiority of the immune response and to evaluate the safety of the RSVPreF3 OA investigational vaccine in adults 18-49 years of age at increased risk of respiratory syncytial virus disease, compared to older adults ≥60 years of age. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC are updated. The Package	11/12/2025	19/01/2026	SmPC and PL	Please refer to Scientific Discussion 'Arexvy-H-C- -II- EMA/VR/0000276225'

	Leaflet is updated in accordance. Version 3.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce minor editorial changes to the PI.				
Variation type II / EMA/VR/0000290199	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.5 of the SmPC to add information on the co-administration with COVID-19 mRNA vaccine based on final report from study RSV OA=ADJ-013. This is a Phase 3, open-label, randomized, controlled study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with a COVID-19 mRNA vaccine (Omicron XBB.1.5) in adults aged 50 years and above. The Package Leaflet is updated accordingly.	16/10/2025	19/01/2026	SmPC and PL	Following the submission of the final study results of study RSV OA=ADJ-013, section 4.5 of the SmPC of Arexvy (RSVPreF3 OA)has been updated to indicate that Arexvy can be co-administered with a COVID-19 mRNA vaccine. Non-inferiority of the co-administration compared to RSVPreF3 OA vaccine administered alone was demonstrated for RSV-A (GMT ratio: 1.12 (95% CI:0.97-1.28)) and RSV-B (GMT:1.08 (95% CI: 0.94 – 1.23)). However, non-inferiority of the co-administration compared to COVID-19 mRNA vaccine administered alone could not be demonstrated based on SARS-CoV-2 neutralising antibodies (GMT ratio: 1.31 (95% CI: 1.13 – 1.51)). The pre-specified non-inferiority margin of 1.5 was slightly exceeded. Of note, an analysis based on the exposed set population met the pre-specified criteria based on SARS-CoV-2 neutralising antibodies (GMT ratio:1.28 (95% CI: 1.11, 1.47)). In the absence of a correlate of protection, the clinical relevance of the reduced response for SARS-CoV-2 is unknown and it should not prevent co-administration of Arexvy and a COVID-19 mRNA vaccine. Co-administration of RSVPreF3 OA and a COVID-19 mRNA vaccine was not associated with a clinically relevant increased risk of ADRs compared to when the vaccines were

					administered separately, and the safety profile of RSVPreF3 OA and COVID-19 mRNA vaccine when co-administered is comparable to the known safety profile of these two vaccines administered alone. For more information, please refer to the Summary of Product Characteristics.
Variation type II / EMA/VR/0000264399	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.5 of the SmPC in order to add information on concomitant use with other vaccines based on final results from study RSV OA=ADJ-020. This is a Phase III, open-label, randomised, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with Herpes Zoster recombinant subunit (HZ/su) vaccine in adults aged 50 years and older. The Package Leaflet is updated accordingly. In addition,	18/09/2025	19/01/2026	SmPC, Labelling and PL	Following the submission of the final study results of study RSV OA=ADJ-020, the section 4.5 of the SmPC of Arexvy and Shingrix has been updated to indicate that both vaccines can be co-administered. The primary objectives were met as non-inferiority was demonstrated for the HZ/su response, as well as for RSV-A and RSV-B. It should be noted that the geometric mean concentrations (GMCs) for anti-gE titers were numerically higher in the control group with sequential administration (61193 %CI: 55306 – 67706) compared to the Co-Ad group with concomitant administration (49327, 95%CI: 44949 – 54132), leading to a GMC ratio of 1.24 (95% CI: 1.08 – 1.42). However, the reverse cumulative distribution curves showed a similar pattern for both groups and the vaccine response rate was comparable, with VRR being 93% (95%CI 88 – 96) in the Co-Ad group and 97% (95% CI: 93-99) in the Control group. Due to the absence of a correlate for protection for anti-gE titers, it is not clear whether the observed difference in anti-gE titers will have a clinically relevant impact. It is considered that the slightly reduced response against HZ/su as observed in the Co-Ad group should not prevent the two vaccines from being given together, also taking

	the MAH took the opportunity to implement editorial changes to the PI.				into consideration the robust immune response still generated. It is noted that similar immunogenicity trends were observed in previous submissions upon concomitant administration of Arexvy with seasonal influenza vaccines, where numerically lower RSV A and B neutralising titres and numerically lower influenza A and B haemagglutination inhibition titres were observed as compared to the separate administration. This was not observed consistently across studies. Similarly, when Shingrix is co-administered with the dTpa vaccine, lower (GMCs) for one of the pertussis antigens (pertactin) was observed. The clinical relevance of this immunogenicity findings is unknown. Co administration of Arexvy and Shingrix was not associated with a clinically relevant increased risk of ADRs compared to when the vaccines were administered separately, and the safety profile of Arexvy and Shingrix co administered is comparable to the known safety profile of these two vaccines administered alone. The statements in 4.5 for co-administration of Arexvy and Shingrix with other vaccines were revised to ensure that only relevant information for prescribers is retained in the SmPC. For more information, please refer to the Summary of Product Characteristics.
Variation type II / EMA/VR/0000284817	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new	18/09/2025	19/01/2026	SmPC and PL	SmPC new text Following the submission of the final study results of study RSV OA=ADJ-019, section 4.5 of the SmPC of Arexvy (RSVPreF3 OA)has been updated to indicate that Arexvy can be co-administered with 20-valent pneumococcal

	quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.5 of the SmPC in order to include the possibility of co-administration of Arexvy with a pneumococcal conjugate vaccine based on results from study RSV OA=ADJ-019. This is a Phase III, open-label, randomized, controlled, multi-country study to evaluate the immune response, safety and reactogenicity of RSVPreF3 OA vaccine when co-administered with 20-valent pneumococcal conjugate vaccine (PCV20) in adults aged 60 years and older. The Package Leaflet is updated accordingly.				conjugate vaccine (PCV20). The primary objectives were met as non-inferiority was demonstrated for RSV-A and RSV-B as well as for the response to all 20 PCV20 serotypes. For RSV-A and RSV-B, adjusted GMT ratios were 1.06 and 1.00, respectively suggesting no interference in the response to RSV-A and RSV-B due to concomitant administration with PCV20. While response to PCV20 was consistently somewhat decreased in the co-administration group, there was still a robust immune response. The clinical relevance of the reduction is not entirely clear, but similar decreases were seen for the co-administration of PCV20 and quadrivalent influenza vaccine and were still in the same range as those observed in the registration study of PCV20. Co-administration of RSVPreF3 OA and PCV20 was not associated with a clinically relevant increased risk of ADRs compared to when the vaccines were administered separately, and the safety profile of RSVPreF3 OA and PCV20 when co-administered is comparable to the known safety profile of these two vaccines administered alone. For more information, please refer to the Summary of Product Characteristics.
Variation type IA / EMA/VR/0000280705	Outcome: B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.z To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients,	31/07/2025			

	active substance starting materials and immediate packaging materials - Accepted				
Variation type IB / EMA/VR/0000278249	Outcome: B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	15/07/2025			
PSUR / EMA/PSUR/0000248473	EURD: PSUSA/00000031/202411 Active substance: respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e Outcome: Variation In view of available data on Guillain-Barré syndrome from clinical trial(s), the literature, spontaneous reports including in some cases a compatible temporal relationship and the information from the SCCS performed by FDA, the PRAC considers that a causal relationship between respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E and Guillain-Barré syndrome is at least a reasonable possibility. The PRAC concluded that the product information of	19/06/2025	18/08/2025	SmPC and PL	Variation

	products containing respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with AS01E should be amended accordingly.				
Variation type II / EMA/VR/0000255022	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from study 219238 (RSV OA=ADJ-018). This is a phase 3, observer-blind, randomized, placebo-controlled study to evaluate the non-inferiority of the immune response and safety of the RSVPreF3 OA investigational vaccine in adults 50-59 years of age, including adults at increased risk of respiratory syncytial virus lower respiratory tract disease, compared to older adults ≥60 years of age.	08/05/2025			
Variation type II / EMA/VR/0000236493	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted	25/04/2025	18/08/2025	SmPC	

	Update of section 5.1 of the SmPC in order to update efficacy information based on final results from study 212494 (RSV OA=ADJ-006). This is a phase 3, randomized, placebo-controlled, observer blind, multi-country study to demonstrate the efficacy of a single dose and annual revaccination of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above. In addition, the MAH took the opportunity to implement editorial changes to the PI.				
Variation type II / EMA/VR/0000232276	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.c.2 Change in test procedure for an excipient - B.II.c.2.c Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent - Accepted	13/02/2025			
Variation type IB / EMA/VR/0000240861	Outcome: B.I.b) Control of active substance - B.I.b.z Other variation - Accepted	10/01/2025			

Variation type IB / EMA/VR/0000236022	Outcome: This was an application for a group of variations. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.z Other changes - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.z Other changes - Accepted	03/12/2024			