AREXVY

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
EMA/VR/0000236493	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	25/04/2025	n/a	SmPC	Final study results of study ADJ-006 provide additional efficacy data over 3 RSV seasosns, which is added to section 5.1 of the SmPC. Over the 3 seasons in the north hemisphere (NH), the estimated vaccine efficacy (VE) in the primary efficacy population adjusted for age, region and season, was 62.9% (97.5% CI: 46.7, 74.8). During season 3 in the NH the estimated VE of a single dose of RSVPreF3 vaccine against RSV-confirmed LRTD was 47.2% (95% CI: 7.1, 71.6%). The results indicate that waning of VE from season 1 to season 3 occurred. However, during season 3 there still seems to be relevant protection. Relevant protection against LRTD caused by

			RSV was indicated by the estimated VE in the most clinically relevant subgroups, although the study was not powered to determine VE in these subgroups. The waning of VE was mirrored in the waning of the neutralising antibody titers. After a single dose of Arexvy, there was a substantial reduction in RSV-A and -B neutralising antibody titers from D31 after dose 1 to pre-season 2 and a still further decline to pre-season 3. However, the titers remained above baseline even pre-season 3. No safety concern was identified. The benefit risk of Arexvy remains favourable. For more information, please refer to the Summary of Product Characteristics.

[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).

	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.				
PSUSA/31/202405	Periodic Safety Update EU Single assessment - respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e	12/12/2024	14/02/2025		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/31/202405.
II/0008	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	25/07/2024	26/08/2024	SmPC and PL	Please refer to Scientific Discussion 'Arexvy-H-C-006054-II-008"
II/0004	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	27/06/2024	26/08/2024	SmPC	
PSUSA/31/202311	Periodic Safety Update EU Single assessment - respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e	16/05/2024	n/a		PRAC Recommendation - maintenance
II/0009/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place,	02/05/2024	n/a		

	except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
II/0002/G	This was an application for a group of variations. Update of section 4.5 of the SmPC in order to update information on the co-administration with inactivated seasonal quadrivalent influenza vaccines: with a high dose unadjuvanted influenza vaccine (QIV-HD) and a standard dose adjuvanted influenza vaccine (aQIV) based on final results from studies ADJ-008 and ADJ-017. These are Phase III studies intended to evaluate the immune response, safety and reactogenicity of Arexvy when co-administered with a high dose unadjuvanted quadrivalent influenza vaccine (QIV-HD,	11/04/2024	26/08/2024	SmPC	Information added to section 4.5 of SmPC (Interaction with other medicinal products and other forms of interaction) (cursive) Use with other vaccines Arexvy may be administered concomitantly with inactivated seasonal influenza vaccines (standard dose unadjuvanted, high dose unadjuvanted, or standard dose adjuvanted). Upon concomitant administration of Arexvy with seasonal influenza vaccines, 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. The clinical relevance of these findings is unknown. If Arexvy is to be given at the same time as another

	study ADJ-008) and a standard dose adjuvanted influenza vaccine (aQIV, study ADJ-017), respectively. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				injectable vaccine, the vaccines should always be administered at different injection sites. Concomitant administration of Arexvy with other vaccines than those listed above has not been studied. For more information, please refer to the Summary of Product Characteristics.
IB/0006/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	01/02/2024	26/08/2024	SmPC	
IB/0003/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished	19/12/2023	n/a		

	product - Other variation		
IG/1677	B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation	27/11/2023	n/a
IB/0001	B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	07/07/2023	n/a