Swiss Summary of the Risk Management Plan (RMP)

for

AREXVY

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

[Respiratory syncytial virus (RSV) pre-fusion protein F (RSVPreF3 antigen)]

RMP Summary: Version 1, June 2024
Marketing Authorisation Holder: GlaxoSmithKline AG

Based on EU RMP version 1.0 (03 May 2023)

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.

The RMP summary of Arexvy is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Arexvy in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic.

GlaxoSmithKline AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Arexvy.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for the RSVPreF3 OA candidate vaccine

This is a summary of the risk management plan (RMP) for *AREXVY*. The RMP details important risks of *AREXVY*, how these risks can be minimized, and how more information will be obtained about *AREXVY*'s risks and uncertainties (missing information).

The *AREXVY*'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how *AREXVY* should be used.

This summary of the RMP for *AREXVY* should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of *AREXVY*'s RMP.

I. The medicine and what it is used for

AREXVY is authorised for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults aged 60 years and above (see SmPC for the full indication). It contains the RSVPreF3 antigen as the active substance and it is given by intramuscular injection.

Further information about the evaluation of *AREXVY*'s benefits can be found in *AREXVY*'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/arexvy

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of *AREXVY*, together with measures to minimise such risks and the proposed studies for learning more about *AREXVY*'s risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine's legal status — the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation measures*.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of *AREXVY* are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of *AREXVY*. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of *AREXVY*.

II.C.2 Other studies in post-authorization development plan

There are no studies required for *AREXVY*.