EMA/CHMP/141401/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Arexvy

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

On 26 April 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Arexvy, intended for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in adults 60 years of age or older. Arexvy was reviewed under EMA's accelerated assessment programme.

The applicant for this medicinal product is GlaxoSmithkline Biologicals S.A.

Arexvy will be available as a powder and suspension liquid to be made into a suspension for injection. The active substance of Arexvy is RSVPreF3, a recombinant RSV-specific antigen glycoprotein F stabilised in the pre-fusion conformation (ATC code: not yet assigned). RSVPreF3 is combined with the $AS01_E$ adjuvant system (strengthening the immune response); the vaccine is designed to enhance the antigen-specific cellular immune response and neutralising antibodies response in individuals with pre-existing immunity against RSV.

The benefit of Arexvy is the prevention of RSV-confirmed lower respiratory tract disease. The most common side effects are injection site pain, fatigue, myalgia, headache and arthralgia.

The full indication is:

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

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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