27 June 2024
EMA/CHMP/285703/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

mResvia

Respiratory Syncytial Virus (RSV) mRNA vaccine

On 27 June 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product mResvia, intended for the prevention of lower respiratory tract (LRT) disease caused by respiratory syncytial virus (RSV). The applicant for this medicinal product is Moderna Biotech Spain S.L.

mResvia will be available as a dispersion for injection. mResvia is an mRNA vaccine (ATC code: J07BX05) containing single-stranded 5' capped mRNA encoding RSV glycoprotein F stabilised in the prefusion conformation. The prefusion F glycoprotein is the target of neutralising antibodies that mediate protection against RSV-associated respiratory tract disease. mResvia stimulates production of RSV A and RSV B neutralising antibodies and induction of antigen-specific cellular immune responses.

The benefit of mResvia is the prevention of RSV-confirmed lower respiratory tract disease in adults 60 years of age and older, as shown in a phase 2/3 randomised, placebo-controlled study. The most common side effects are injection site pain, fatigue, headache, myalgia and arthralgia.

The full indication is:

> mRESVIA 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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