



21 July 2022  
EMA/CHMP/620586/2022  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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# Tezspire

## tezepelumab

On 21 July 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tezspire, intended as add-on treatment in adult and adolescent patients with severe asthma. The applicant for this medicinal product is AstraZeneca AB.

Tezspire will be available as a 210 mg solution for injection. The active substance of Tezspire is tezepelumab, a human monoclonal antibody (IgG2 lambda) directed against thymic stromal lymphopoietin (TSLP) (ATC code: R03DX11). Blocking TSLP with tezepelumab reduces a broad spectrum of biomarkers and cytokines associated with airway inflammation, but the mechanism of action of tezepelumab in asthma has not been definitively established.

The benefits of Tezspire are its ability to reduce the exacerbation rate and improve lung function in patients with severe asthma. The most common side effects are pharyngitis, rash, arthralgia and injection site reactions.

The full indication is:

Tezspire is indicated as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.

Tezspire should be prescribed by physicians experienced in the treatment of severe asthma.

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

