11 December 2025
EMADOC-1829012207-35814
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Exdensur

depemokimab

On 11 December 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Exdensur, intended for severe eosinophilic asthma and for severe chronic rhinosinusitis with nasal polyps (CRSwNP).

The applicant for this medicinal product is GlaxoSmithKline Trading Services Limited.

Exdensur will be available as a 100 mg solution for injection in pre-filled pen or syringe, for subcutaneous administration. The active substance of Exdensur is depemokimab, a systemic drug for obstructive airways diseases (ATC code: R03DX12). Depemokimab is a monoclonal antibody targeting interleukin 5 (IL-5). By preventing IL-5 to bind to the IL-5 receptor, depemokimab is expected to reduce inflammation in patients with eosinophilic asthma and CRSwNP.

The full indication is:

> Asthma
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> EXDENSUR is indicated as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by blood eosinophil count in adults and adolescents 12 years and older who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller (see section 5.1).
>
> Chronic rhinosinusitis with nasal polyps (CRSwNP)
>
> EXDENSUR is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Exdensur should be prescribed by physicians experienced in the diagnosis and treatment of asthma or CRSwNP.

[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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The main evidence of efficacy of Exdensur in severe asthma is based on two replicate Phase III clinical studies (SWIFT-1 and SWIFT-2). The studies were conducted in patients aged 12 years and older with uncontrolled severe asthma with an eosinophilic phenotype (defined by elevated blood eosinophil count) despite treatment with inhaled corticosteroids and an additional controller medication. The two studies met their primary endpoint by showing superiority of 100 mg depemokimab over placebo (both in addition to standard of care) in the annualised rate of clinically significant exacerbations. The main evidence of efficacy of Exdensur in CRSwNP is based on two replicate Phase III studies (ANCHOR-1 and ANCHOR-2). The studies were conducted in patients with symptomatic and severe CRSwNP whose disease was not controlled despite the use of intra-nasal corticosteroids and who had prior treatment with systemic corticosteroid within the past 2 years, and/or had a documented history of prior surgery for CRSwNP or had contra-indications for these treatments. The two studies met their co-primary endpoints by showing superiority of 100 mg depemokimab over placebo (both in addition to standard of care) in the endoscopic nasal polyps score and nasal obstruction verbal rating score. The pooled analyses showed a numerical delay in the time to first nasal surgery (actual or on waiting list) and need for initiation of other maintenance treatments impacting type 2 inflammation.

The most relevant safety concern was use in pregnant patients and the most commonly reported adverse reactions were local injection site reactions (2%).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.