21 March 2024
EMA/CHMP/117126/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Omlyclo

omalizumab

On 21 March 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 Omlyclo, intended for the treatment of severe persistent allergic asthma, severe chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic spontaneous urticaria (CSU).

The applicant for this medicinal product is Celltrion Healthcare Hungary Kft.

Omlyclo will be available as 75 mg and 150 mg solution for injection in pre-filled syringe. The active substance of Omlyclo is omalizumab, a drug for obstructive airway diseases (ATC code: R03DX05). Omalizumab is a recombinant DNA-derived humanised monoclonal antibody that selectively binds to human immunoglobulin E (IgE), thereby reducing the amount of free IgE available to trigger the allergic cascade.

Omlyclo is a biosimilar medicinal product. It is highly similar to the reference product Xolair (omalizumab), which was authorised in the EU on 25 October 2005. Data show that Omlyclo has comparable quality, safety and efficacy to Xolair. More information on biosimilar medicines can be found here.

The full indication is:

> Allergic asthma
>
> Omlyclo is indicated in adults, adolescents and children (6 to <12 years of age).
>
> Omlyclo treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma (see section 4.2).
>
> *Adults and adolescents (12 years of age and older)*
>
> Omlyclo is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial

[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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aeroallergen and who have reduced lung function (FEV1 <80%) as well as frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Children (6 to <12 years of age)

Omlyclo is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Omlyclo is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe CRSwNP for whom therapy with INC does not provide adequate disease control.

Chronic spontaneous urticaria (CSU)

Omlyclo is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.

Omlyclo should be prescribed by physicians experienced in the treatment of severe persistent asthma, CRSwNP or CSU.

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.