27 June 2024
EMA/CHMP/289588/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Winrevair

sotatercept

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 Winrevair[2], intended for the treatment of pulmonary arterial hypertension (PAH). The applicant for this medicinal product is Merck Sharp & Dohme B.V.

Winrevair will be available as 45 mg and 60 mg powder and solvent for solution for injection and 45 mg and 60 mg powder for solution for injection. The active substance of Winrevair is sotatercept, an antihypertensive for pulmonary arterial hypertension (ATC code: C02KX06). Sotatercept is a human recombinant fusion protein. It acts as a ligand trap that scavenges excess Activin A, which is increased in PAH patients, to inhibit activin signalling thereby modulating vascular cell proliferation, decreasing pulmonary vascular resistance and improving haemodynamics.

The benefit of Winrevair in patients with PAH on background therapy is an improvement in 6-minute walk distance (6MWD) compared with placebo, as observed in a randomised, double-blind, placebo-controlled study. Sotatercept was generally well-tolerated and had a manageable safety profile; however, treatment was associated with increased haemoglobin (erythrocytosis) and a decreased platelet count (thrombocytopenia), both of which were manageable by dose modification. The most common side effects are headache and nosebleeds.

The full indication is:

> Winrevair, in combination with other pulmonary arterial hypertension (PAH) therapies, is indicated for the treatment of PAH in adult patients with WHO Functional Class (FC) II to III, to improve exercise capacity.

Winrevair should be prescribed by physicians experienced in the diagnosis and treatment of PAH.

Detailed recommendations for the use of this product will be described in the summary of product

[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
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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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.