19 September 2024
EMA/423564/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Hympavzi

marstacimab

On 19 September 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 Hympavzi[2], intended for prophylaxis of bleeding episodes in patients aged 12 years and older, weighing at least 35 kg, who have severe haemophilia A or B.

The applicant for this medicinal product is Pfizer Europe Ma EEIG.

Hympavzi will be available as 150 mg solution for injection. The active substance of Hympavzi is marstacimab, an antihemorrhagic (ATC code: B02BX11). Marstacimab is a human monoclonal antibody which inhibits the anticoagulation function of TFPI. By enhancing the extrinsic pathway and bypassing deficiencies in the intrinsic pathway of coagulation, marstacimab increases free factor Xa availability, thereby increasing thrombin generation and promoting haemostasis.

The benefit of Hympavzi is the prevention of bleeding in severe haemophilia A or severe haemophilia B patients when given as prophylaxis. This benefit was demonstrated in a 12-month non-inferiority clinical study comparing the effects of marstacimab on bleeding frequency with routine factor-based prophylaxis. The most common side effects with Hympavzi are injection site reactions, headache, hypertension, and pruritus.

The full indication is:

> Hympavzi is indicated for routine prophylaxis of bleeding episodes in patients 12 years of age and older, weighing at least 35 kg, with:
>
> - severe haemophilia A (congenital factor VIII deficiency, FVIII < 1%) without factor VIII inhibitors, or
> - severe haemophilia B (congenital factor IX deficiency, FIX < 1%) without factor IX inhibitors.

[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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Hympavzi should be prescribed and supervised by physicians experienced in the treatment of haemophilia. Treatment with Hympavzi should be started in a non-bleeding state.

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.