20 September 2018
EMA/CHMP/637902/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Jivi

damoctocog alfa pegol

On 20 September 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Jivi, intended for the treatment of haemophilia A (congenital factor VIII deficiency). Jivi was designated as an orphan medicinal product on 23 February 2011. The applicant for this medicinal product is Bayer AG.

Jivi will be available as powder and solvent for solution for injection (250 IU, 500 IU, 1000 IU, 2000 IU and 3000 IU). The active substance of Jivi is damoctocog alfa pegol, a recombinant human factor VIII (ATC code: B02BD02), which replaces the missing coagulation factor VIII needed for effective haemostasis.

The benefits with Jivi are its ability to prevent and control bleeding when used on demand and during surgical procedures, as seen in clinical trials in adult and paediatric patients with haemophilia A. The most common side effects are hypersensitivity, insomnia, headache, dizziness, cough, abdominal pain, nausea, vomiting, erythema, rash, infusion site reactions and pyrexia.

The full indication is: "Treatment and prophylaxis of bleeding in previously treated patients ≥ 12 years of age with haemophilia A (congenital factor VIII deficiency)."

It is proposed that Jivi be prescribed by physicians experienced in the treatment of haemophilia.

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.

[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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