9 November 2017
EMA/CHMP/737340/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Prevymis

letermovir

On 9 November 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Prevymis, intended for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT). Prevymis was designated as an orphan medicinal product on 15 April 2011. The applicant for this medicinal product is Merck Sharp & Dohme Limited.

Prevymis will be available as a concentrate for solution for infusion and as film-coated tablets (240 mg and 480 mg). The active substance of Prevymis is letermovir, an antiviral (ATC code: J05AX18) that acts on the CMV DNA terminase and inhibits viral replication.

The benefits with Prevymis are its ability to prevent reactivation of CMV infection (CMV DNAemia) and CMV end-organ disease in a population of HSCT patients at risk of CMV reactivation. The most common side effects are nausea, diarrhoea and vomiting.

The full indication is: "Prevymis is indicated for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT)."

It is proposed that Prevymis be prescribed by physicians experienced in the management of patients who have had an allogeneic haematopoietic stem cell transplant.

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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