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Public statement

Ritemvia

Withdrawal of the marketing authorisation in the European Union

On 22 June 2021, the European Commission withdrew the marketing authorisation for Ritemvia (rituximab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Celltrion Healthcare Hungary Kft., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Ritemvia was granted marketing authorisation in the EU on 13 July 2017 for the treatment of non-Hodgkin's lymphoma (NHL), granulomatosis with polyangiitis and microscopic polyangiitis, and pemphigus vulgaris (PV). The marketing authorisation was initially valid for a 5-year period.

Ritemvia is a biosimilar medicine of MabThera. There are other biosimilar medicinal products of MabThera authorised and marketed in the EU. MabThera is authorised in the EU to treat non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL), rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis, and pemphigus vulgaris. Ritemvia was a duplicate of Truxima which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for another duplicate, Blitzima.

The European Public Assessment Report (EPAR) for Ritemvia will be updated to indicate that the marketing authorisation is no longer valid.

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