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Public statement

Rituzena

Withdrawal of the marketing authorisation in the European Union

On 10 April 2019, the European Commission withdrew the marketing authorisation for Rituzena (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 not to market the product in the EU for commercial reasons.

Rituzena was granted marketing authorisation in the EU on 13 July 2017 for treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, granulomatosis with polyangiitis and microscopic polyangiitis. The marketing authorisation was initially valid for a 5-year period.

Rituzena is a biosimilar of MabThera. There are other biosimilar medicinal products of MabThera authorised and marketed in the EU. Rituzena was a duplicate application to Truxima, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Truxima and the other duplicates Ritemvia and Blitzima.

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European Public Assessment Report (EPAR) for Rituzena will be updated to indicate that the marketing authorisation is no longer valid.

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