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Public statement

Arzerra

Withdrawal of the marketing authorisation in the European Union

On 28 February 2019, the European Commission withdrew the marketing authorisation for Arzerra (ofatumumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Novartis Europharm Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Arzerra was granted marketing authorisation in the EU on 19 April 2010 for the treatment of chronic lymphocytic leukaemia (CLL). The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2015.

The European Public Assessment Report (EPAR) for Arzerra will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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