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Public statement

Lextemy

Withdrawal of the marketing authorisation in the European Union

On 21 June 2021, the European Commission withdrew the marketing authorisation for Lextemy (bevacizumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Mylan IRE Healthcare Limited, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Lextemy was granted marketing authorisation in the EU on 21 April 2021 for treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer and recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer, first-line treatment of patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer, first line treatment of patients with advanced and/or metastatic renal cell cancer. The marketing authorisation was initially valid for a 5-year period.

Lextemy was a duplicate application to Abevmy, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Abevmy.

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European Public Assessment Report (EPAR) for Lextemy will be updated to indicate that the marketing authorisation is no longer valid.

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