

10 July 2017 EMA/428877/2017 EMEA/H/C/000972

Public statement

Removab

Withdrawal of the marketing authorisation in the European Union

On 2 June 2017, the European Commission withdrew the marketing authorisation for Removab (catumaxomab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Neovii Biotech GmbH, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Removab was granted marketing authorisation in the EU on 20 April 2009 for treatment of malignant ascites in adults with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2013. The product had not been marketed in the EU since 2014

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Report (EPAR) for Removab will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

