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Public statement

Onbevzi (bevacizumab)

Withdrawal of the marketing authorisation in the European Union

On 11 December 2023, the European Commission withdrew the marketing authorisation for Onbevzi (bevacizumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Samsung Bioepis NL B.V., which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Onbevzi was granted marketing authorisation in the EU on 11 January 2021 for the treatment of carcinoma of the colon or rectum, breast cancer, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube or primary peritoneal cancer, and carcinoma of the cervix. The marketing authorisation was initially valid for a 5-year period.

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

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European Public Assessment Report (EPAR) for Onbevzi will be updated to indicate that the marketing authorisation is no longer valid.

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