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Public statement

Gavreto (pralsetinib)

Withdrawal of the marketing authorisation in the European Union

On 24 October 2024, the European Commission withdrew the marketing authorisation for Gavreto (pralsetinib) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Blueprint Medicines (Netherlands) B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Gavreto was granted a conditional marketing authorisation in the EU on 18 November 2021 for the treatment of non-small cell lung cancer (NSCLC).

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European Public Assessment Report (EPAR) for Gavreto will be updated to indicate that the marketing authorisation is no longer valid.

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