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Public statement

Varuby (rolapitant)

Withdrawal of the marketing authorisation in the European Union

On 23 January 2020 the European Commission withdrew the marketing authorisation for Varuby (rolapitant) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Tesaro Bio Netherlands B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Varuby was granted marketing authorisation in the EU on 20 April 2017 for the prevention of nausea and vomiting. The marketing authorisation was initially valid for a 5-year period.

The European Public Assessment Report (EPAR) for Varuby will be updated to indicate that the marketing authorisation is no longer valid.

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