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Public statement

Zynteglo

Withdrawal of the marketing authorisation in the European Union

On 24 March 2022, the European Commission withdrew the marketing authorisation for Zynteglo (betibeglogene autotemcel) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, bluebird bio (Netherlands) B.V, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Zynteglo was granted conditional marketing authorisation in the EU on 29 May 2019 for treatment of transfusion-dependent β-thalassaemia (TDT). The marketing authorisation was initially valid for a 1 year period. It was subsequently renewed for an additional 1-year period in 2020 and 2021.

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European Public Assessment Report (EPAR) for Zynteglo will be updated to indicate that the marketing authorisation is no longer valid.

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