EUROPEAN MEDICINES AGENCY
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**Public statement**

# Skysona

## Withdrawal of the marketing authorisation in the European Union

On 18 November 2021, the European Commission withdrew the marketing authorisation for Skysona (elivaldogene 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 not to market the product in the EU for commercial reasons.

Skysona was granted marketing authorisation in the EU on 16 July 2021 for treatment of early cerebral adrenoleukodystrophy. No patients had been treated with Skysona since its marketing authorisation.

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European Public Assessment Report (EPAR) for Skysona will be updated to indicate that the marketing authorisation is no longer valid.

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