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Public statement

Zalmoxis (nalotimagene carmaleucel)

Withdrawal of the marketing authorisation in the European Union

On 9 October 2019, the European Commission withdrew the marketing authorisation for Zalmoxis (nalotimagene carmaleucel) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, MolMed S.p.A, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Zalmoxis (nalotimagene carmaleucel) was granted marketing authorisation in the EU on 18 August 2016 as adjunctive treatment in haploidentical haematopoietic stem cell transplantation (HSCT) of adult patients with high-risk haematological malignancies. This was a conditional marketing authorisation and was subsequently renewed yearly.

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Report (EPAR) for Zalmoxis (nalotimagene carmaleucel) will be updated to indicate that the marketing authorisation is no longer valid.

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