27 July 2016

Public statement

Osigraft

On 17 December 2015, the European Commission withdrew the marketing authorisation for Osigraft (eptotermin alfa) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Olympus Biotech International Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Osigraft was granted marketing authorisation in the EU on 17 May 2001 for treatment of non-union of the tibia. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2006. It was then granted unlimited validity in 2011.

The European Public Assessment Report (EPAR) for Osigraft will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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