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Public statement

Provenge

Withdrawal of the marketing authorisation in the European Union

On 6 May 2015, the European Commission withdrew the marketing authorisation for Provenge (autologous peripheral blood mononuclear cells activated with PAP-GM-CSF (sipuleucel-T)) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Dendreon UK Ltd, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Provenge was granted marketing authorisation in the EU on 6 September 2013 for treating men with asymptomatic or minimally symptomatic metastatic (non-visceral) castrate-resistant prostate cancer in whom chemotherapy is not yet clinically indicated. The marketing authorisation was initially valid for a 5-year period.

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Report (EPAR) for Provenge will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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