



22 October 2015
EMA/690530/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Imlygic

talimogene laherparepvec

On 22 October 2015 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Imlygic, intended for the treatment of melanoma. The applicant for this medicinal product is Amgen Europe B.V.

Imlygic will be available as a solution for injection (1x 10⁶ PFU/ml and 1x 10⁸ PFU/ml). The active substance of Imlygic is talimogene laherparepvec, an oncolytic virus derived from HSV-1. The virus has been modified to replicate within tumours and to produce the immune stimulatory protein human GM-CSF, which promotes a systemic anti-tumour immune response and an effector T-cell response.

Imlygic has been shown to increase the durable response rate (DRR) compared with GM-CSF treatment with a DRR of 25.2% compared to 1.2%, respectively, in patients with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease.

The most common side effects are fatigue, chills, pyrexia, nausea, influenza-like illness and injection site pain. Imlygic is not to be used in patients who are severely immunocompromised (e.g. patients with severe congenital or acquired cellular and/or humoral immune deficiency).

The full indication is: "Imlygic is indicated for the treatment of adults with unresectable melanoma that is regionally or distantly metastatic (Stage IIIB, IIIC and IVM1a) with no bone, brain, lung or other visceral disease (see section 4.4 and 5.1)." It is proposed that Imlygic be initiated and supervised by a qualified physician experienced in the treatment of cancer.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

