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Press Office

**Press release**

# European Medicines Agency recommends approval of first-in-class treatment for metastatic or unresectable melanoma

## Novel protein-kinase inhibitor recommended for treatment of melanoma patients with BRAF V600 mutations

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the granting of a marketing authorisation for a novel protein-kinase inhibitor to treat patients suffering from metastatic or unresectable melanoma with BRAF V600 mutations.

Melanoma is the sixth most common malignancy in men and the seventh most common malignancy in women. In Europe, doctors diagnose almost 60,000 new cases of melanoma per year. Approximately 8,300 men and 7,600 women die from this type of cancer every year. When detected and treated early, patients with localised melanoma have an excellent prognosis, with a survival rate of more than 90%. However, for patients with unresectable or metastatic melanoma, the prognosis remains poor: it is estimated that only 25.5% of patients diagnosed with this type of disease are still alive one year after first diagnosis; five years after the first diagnosis, less than 15% of patients are still alive.

There is a high unmet medical need for alternative treatments for metastatic melanoma that improve survival of patients. In the pivotal clinical trial, Zelboraf (vemurafenib), the new protein-kinase inhibitor, was compared to the standard first-line treatment of dacarbazine. The medicine was shown to improve progression-free survival (PFS) by about 4 months (5.3 months for vemurafenib compared to 1.6 months for dacarbazine) and overall survival (OS) by about 3 months (13.2 months for vemurafenib compared to 9.9 months for dacarbazine) in patients who tested positive for BRAF V600 mutations.

In its assessment, the CHMP also looked at potential side effects of Zelboraf. The Committee considered that although there was a risk of secondary neoplasms, most notably squamous cell carcinoma of the skin (cuSCC), the magnitude of the risk was likely to be low. The Committee also noted that the applicant's risk-management plan for this medicine detailed adequate risk-minimisation measures and the product information contained appropriate information so that cuSCC can be managed in clinical practice, e.g. by routine monitoring during treatment.

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Following review of all available data, the Committee concluded during its December 2011 meeting that the benefits of Zelboraf, particularly the improvements seen in terms of PFS and OS of patients, outweigh its risks, and recommended that a marketing authorisation should therefore be granted.

## Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The CHMP's recommendation is now being sent to the European Commission for the adoption of a binding decision.
3. The review of Zelboraf began in May 2011, with an active review time by the CHMP of 180 days.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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