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Press Office

Press release

European Medicines Agency recommends approval of Tafinlar for the treatment of metastatic melanoma

The medicine is the second BRAF inhibitor to receive a positive opinion in the EU

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorisation for Tafinlar (dabrafenib) for the treatment of adult patients with advanced (unresectable or metastatic) melanoma expressing a BRAF V600 gene mutation.

Melanoma is the sixth most common malignancy in men and the seventh most common in women. In Europe, every year, doctors diagnose almost 60,000 new cases and approximately 8,300 men and 7,600 women die from this cancer. Cutaneous melanoma, the most common form of melanoma, is also the most aggressive type of skin cancer, with a median survival time for patients with stage IV melanoma of approximately 6 months.

For decades, cytotoxic chemo- and immunotherapy have been the mainstays of systemic therapy for unresectable melanoma. The therapeutic landscape for the treatment of metastatic melanoma in the European Union has changed significantly in recent years with the granting of marketing authorisations for new targeted active agents: one of them, the monoclonal antibody ipilimumab, targets a molecule found on the surface of T cells and is thought to inhibit immune responses; another agent, vemurafenib, is a first-in-class protein kinase inhibitor, which inhibits the BRAF serine-threonine kinase with a genetic mutation at position 600 (BRAF V600E).

Tafinlar is the second BRAF inhibitor to be recommended for marketing authorisation in the EU.

Mutations of the protein kinase BRAF have been identified in about one half of patients with metastatic melanoma, with the BRAF V600E mutation found in about 80 to 90% of these. These mutations cause the cell to make an abnormal protein that promotes cancer growth. By blocking the action of this abnormal protein, BRAF inhibitors such as Tafinlar help slow down the growth and spread of tumours bearing the BRAF V600 mutation.

Tafinlar has been shown to delay the progression of the disease and to improve the response rate compared with dacarbazine, which is commonly used as single-agent chemotherapy in the treatment of metastatic melanoma. Tafinlar is given orally and is indicated as monotherapy.

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The marketing-authorisation holder for Tafinlar is GlaxoSmithKline.

The applicant received scientific advice from the CHMP in November 2011. The scientific advice pertained to non-clinical and clinical aspects of the dossier.

The CHMP opinion on Tafinlar will now be sent to the European Commission for adoption of a marketing-authorisation decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001836.jsp&mid=WC0b01ac058004d5c1
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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