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Press Office

Press release

European Medicines Agency recommends approval of Mekinist for the treatment of melanoma

First MEK 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 Mekinist (trametinib) for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Mekinist is the first cancer treatment that selectively targets the MEK protein kinase.

Melanoma is the most aggressive type of skin cancer and the leading cause of death from skin disease. In Europe, every year, doctors diagnose almost 60,000 new cases and approximately 16,000 people die from the cancer. Patients with unresectable or metastatic melanoma have a poor prognosis with an average overall survival of approximately one year for stage IIIc or IV of the disease.

For decades, chemotherapy and immunotherapy have been the mainstays of systemic therapy for unresectable and metastatic melanoma, however, the therapeutic landscape in the European Union (EU) has changed significantly in recent years with the authorisation of targeted treatments, including a monoclonal antibody (ipilimumab) that targets a molecule found on the surface of T cells and two medicines (vemurafenib and dabrafenib) that target the BRAF protein kinases with a genetic mutation at position 600.

Mutations of the BRAF protein kinase have been identified in about 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.

The BRAF protein activates a protein kinase known as MEK. By inhibiting the MEK protein kinase, Mekinist blocks the effect of the BRAF mutations that promote cancer growth.

In clinical trials in melanoma patients with BRAF V600 mutation, Mekinist demonstrated superior efficacy compared with chemotherapies. In addition, its benefits with regard to progression-free survival and overall survival were comparable to the results previously reported for BRAF inhibitors while the overall response rates seemed to be lower with the MEK inhibitor. Mekinist represents a new treatment option for these patients.

The applicant for Mekinist is GlaxoSmithKline. The company received scientific advice from the CHMP during the development of the medicine.

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

Notes

1. This press release, together with all related documents, is available on the Agency's website.
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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