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Press Office

Press release

New treatment option recommended for patients with advanced melanoma

Keytruda extends range of treatment options for melanoma patients with poor prognosis

The European Medicines Agency (EMA) has recommended granting a marketing authorisation for Keytruda (pembrolizumab). It is recommended as monotherapy for the treatment of adult patients with advanced melanoma that cannot be surgically removed or where the cancer has spread to other parts of the body (unresectable or metastatic melanoma).

Melanoma is the most aggressive form of skin cancer and the leading cause of death from skin disease. The main risk factor for developing melanoma is ultraviolet (UV) light and intermittent exposure to the sun. In 2012 more than 100,000 Europeans were diagnosed with melanoma and around 22,200 were estimated to have died from the disease.

If melanoma is detected early, it can often be removed by surgery and patients have a very good chance of survival. However, patients with advanced melanoma have a poor prognosis. It is estimated that five years after diagnosis of advanced melanoma only 10 to 30% of patients will still be alive.

For decades, standard chemotherapy was the only available treatment for patients with advanced melanoma. However, this therapy has limited benefits for patients with this disease. In the last three years, the authorisation of targeted treatments, including monoclonal antibodies, BRAF V600 inhibitors and MEK inhibitors, have significantly changed the therapeutic landscape and increasingly benefited patients. However, there are still important unmet medical needs for this condition and the availability of new treatment options continues to be essential to improve the outlook for patients.

Keytruda's active ingredient is pembrolizumab, a humanised monoclonal anti-programmed cell death-1 (PD-1) antibody. Pembrolizumab is a type of immunotherapy, which works by blocking a cellular pathway that limits the immune system from fighting melanoma cells. By blocking this pathway, pembrolizumab enables the body's own immune system to fight the disease.

The Committee for Medicinal Products for Human Use (CHMP) based its recommendation for Keytruda on one uncontrolled study and on early results from two ongoing randomised controlled trials (one comparing Keytruda with standard chemotherapy and the other comparing Keytruda with ipilimumab, another melanoma treatment). The Committee considered that the studies demonstrate the efficacy of

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Keytruda, both in patients who had not previously received ipilimumab and in patients who had previously received ipilimumab.

The Committee also looked at safety information from over 1,000 patients enrolled in clinical studies and considered that the safety profile of Keytruda appears manageable. A follow-up plan to monitor the safety and efficacy of Keytruda was agreed by the CHMP.

The applicant received scientific advice on quality and clinical aspects of the application from the CHMP. This is one of the Agency's main tools to facilitate and stimulate research and development within the EU.

The opinion adopted by the CHMP at its May 2015 meeting is an intermediary step on Keytruda's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, each Member State will take a decision on price and reimbursement based on the potential role/use of this medicine in the context of its national health system.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Keytruda is Merck Sharp & Dohme Limited.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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