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EMA recommends MSD's melanoma drug

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Singapore: European Medicines Agency (EMA) has recommended granting a marketing authorization for Merck Sharp And Dohme's Keytruda (pembrolizumab) as monotherapy for the treatment of adult patients with advanced melanoma that cannot be surgically removed.

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.

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 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.