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EU recommends Opdivo as monotherapy for advance melanoma

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Singapore: European Medicines Agency (EMA) has recommended granting a marketing authorisation for Bristol-Myers Squibb's Opdivo (nivolumab) as monotherapy for the treatment of adult patients with advanced melanoma.

Melanoma is the most aggressive type of skin cancer and the leading cause of death from skin disease. The main risk factor for developing melanoma is ultraviolet light and intermittent exposure to the sun.

For decades, chemotherapy was the standard treatment for patients with advanced melanoma, but it did not improve survival. In the last three years, the authorisation of targeted treatments, including monoclonal antibodies, BRAF V600 and MEK inhibitors, have significantly changed the therapeutic landscape.

The active substance in Opdivo (nivolumab) is a monoclonal antibody. Nivolumab attaches to and blocks a receptor called 'programmed death-1' (PD-1). By blocking the usual receptor interactions, Opdivo leads to activation of the immune system to kill melanoma cells. Opdivo is the first cancer treatment selectively targeting PD-1 recommended for approval in the European Union (EU).

Opdivo's recommendation is based on two main studies in patients with advanced malignant melanoma.