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ASIA EDITION

US FDA approves first cell therapy to treat patients with metastatic melanoma

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US FDA has granted the approval of Amtagvi to US-based Iovance Biotherapeutics Inc

The US Food and Drug Administration (FDA) has approved Amtagvi, the first cellular therapy indicated for the treatment of adult patients with a type of skin cancer (melanoma) that is unable to be removed with surgery (unresectable) or has spread to other parts of the body (metastatic) that previously has been treated with other therapies (a PD-1 blocking antibody, and if *BRAF* V600 mutation positive, a *BRAF* inhibitor with or without a MEK inhibitor).

Treatment for unresectable or metastatic melanoma may include immunotherapy using PD-1 inhibitors, which are antibodies targeting certain proteins in the body to help the immune system fight off cancer cells. In addition, drugs targeting the*BRAF* gene, which helps with managing the growth and functioning of cells, may be used for treating melanoma associated with *BRAF* gene mutations. Those patients whose melanoma has progressed with these therapies have a high unmet medical need.

Amtagvi is a tumour-derived autologous T cell immunotherapy composed of a patient's own T cells, a type of cell that helps the immune system fight cancer. A portion of the patient's tumour tissue is removed during a surgical procedure prior to treatment. The patients' T cells are separated from the tumour tissue, further manufactured and then returned to the same patient as a single dose for infusion. This is the first US FDA-approved tumour-derived T cell immunotherapy.