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Taiwan approves Ono Pharma's non-small cell lung cancer drug with chemotherapy

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Opdivo intravenous infusion approved for neoadjuvant treatment of resectable non-small cell lung cancer in combination with chemotherapy in Taiwan

Japanese firm Ono Pharmaceutical has received the approval of Opdivo (nivolumab) Intravenous Infusion, a human anti-human PD-1 monoclonal antibody, in Taiwan from the Taiwan Food and Drug Administration (TFDA), for neoadjuvant treatment of adult patients with resectable (tumors ?4cm or node positive) and without EGFR or ALK genomic tumor aberrations non-small cell lung cancer in combination with platinum-doublet chemotherapy.

This approval is based on the results from a global multi-centre, randomised, open-label Phase 3 clinical trial, CheckMate -816 trial (ONO-4538-55), evaluating Opdivo in combination with chemotherapy compared to chemotherapy alone as a neoadjuvant treatment in patients with resectable non-small cell lung cancer (NSCLC).

In this trial, three cycles of Opdivo in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoints of event-free survival (EFS) as assessed by Blinded Independent Central Review (BICR) and pathologic complete response (pCR) as assessed by Blinded Independent Pathology Review (BIPR) versus chemotherapy alone when given before surgery. The safety profile of Opdivo in combination with chemotherapy of this trial was consistent with previously reported studies in patients with NSCLC.

In Taiwan, it is estimated that about 16,000 cases are newly diagnosed with lung cancer per year, with approximately 10,000 deaths per year resulting from the disease, showing the first leading cause of cancer-related death. Curative surgery is performed in patients with stages I - IIIA and some patients with stage IIIB NSCLC. However, even if surgery is performed, 30 - 55% of NSCLC patients relapse and die of the disease.