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Ono Pharma's Opdivo intravenous infusion wins additional approval in Taiwan

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Approval is based on results from the CheckMate-77T trial



Japan-based Ono Pharmaceutical has announced that Ono Pharma Taiwan, a Taiwanese subsidiary of Ono, has received the additional approval of OPDIVO® Intravenous Infusion, an anti-PD-1 antibody, from the Taiwan Food and Drug Administration (TFDA), for the neoadjuvant treatment of adult patients with resectable (tumours ?4 cm or node positive) Non-Small Cell Lung Cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements in combination with platinum-doublet chemotherapy, followed by single-agent OPDIVO as adjuvant treatment after surgery.

In Taiwan, it is estimated that approximately 20,000 cases are newly diagnosed with lung cancer per year, with approximately 10,000 deaths resulting from the disease per year, showing the first leading cause of cancer-related death. For some non-metastatic early-stage NSCLC patients, surgery may be able to be used as a singular option for treatment. However, 30% to 55% of patients can develop recurrence, contributing to a need for treatment options administered before surgery (neoadjuvant) and after surgery (adjuvant) to improve long-term outcomes.

In 2011, through a collaboration agreement with Bristol Myers Squibb (BMS), Ono granted BMS its territorial rights to develop and commercialise OPDIVO globally except in Japan, South Korea and Taiwan, where Ono had retained all rights to OPDIVO except the US at the time.

In July 2014, Ono and BMS further expanded the companies' strategic collaboration agreement to jointly develop and commercialise multiple immunotherapies – as single agent and combination regimens – for patients with cancer in Japan, South Korea and Taiwan