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Ono Pharma receives approval for mAb treatment of NSCLC in South Korea

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Opdivo intravenous infusion approved for neoadjuvant treatment of resectable non-small cell lung cancer (NSCL) in combination with chemotherapy in South Korea

Japan's Ono Pharmaceutical has announced that its Korean subsidiary of ONO, has received the approval of Opdivo (nivolumab) Intravenous Infusion (Opdivo), a human anti-human PD-1 monoclonal antibody (mAb), on October 26, 2022 from the Ministry of Food and Drug Safety (MFDS) in South Korea, for neoadjuvant treatment of adult patients with resectable (tumors ?4cm or node positive) non-small cell lung cancer in combination with platinum-doublet chemotherapy.

This approval is based on the results from a global multi-center, randomised, open-label Phase 3 clinical study, CheckMate -816 study (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 study, 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 study was consistent with previously reported studies in patients with NSCLC.