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ONO Submits Supplemental Application for additional OpdivoÃ?Â®

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Intravenous Infusion Monotherapy Dosage and Schedule in Japan Ono Pharmaceutical Co., Ltd. has announced that ONO submitted a supplemental application for a partial change in the approved items of the manufacturing and marketing approval of Opdivo® (generic name: nivolumab) Intravenous Infusion (“Opdivo”), a human anti-human programmed death-1 (PD-1) monoclonal antibody, in Japan to include additional monotherapy dosage and schedule.

This application is aiming to add a dosage and administration of “infuse at 480 mg every 4 weeks over 30 minutes intravenously” to the current dosage and administration of “infuse at 240 mg every 2 weeks over 30 minutes intravenously” in the currently approved indications.

This partial change application will offer additional treatment options for dosage and administration (dose intervals), so it is possible to design a flexible treatment plan according to patient's medical condition and clinical course. In addition, we expect that this will lead to improvement in the convenience of patients and medical staff because the number of visits by patients and the burden on patients and medical staff may be reduced.

Opdivo is a programmed death-1 (PD-1) immune checkpoint inhibitor that is designed to uniquely harness the body’s own immune system to help restore anti-tumor immune response by blocking the interaction between PD-1 and its ligands. By harnessing the body’s own immune system to fight cancer, Opdivo has become an important treatment option across multiple cancers since the approval for the treatment of melanoma in Japan in July 2014. Opdivo is currently approved in more than 65 countries, including Japan, South Korea, Taiwan, China, the US and European Union.