Development Pipeline Progress Status
for 1st Quarter of Fiscal Year Ended March 31, 2016

You can see ONO's development pipeline progress status from page11 through page16 of Flash Report.

■ Progress status after announcement (May 12) regarding financial results of Fiscal Year Ended March 31, 2015

< Development pipeline excluding ONO-4538 (nivolumab)>

○ "Rivastach Patch" for the treatment of alzheimer's disease
The First Committee on New Drugs of Pharmaceutical Affairs and Food Sanitation Council (PAFSC) held on July 31, approved partial changes in the manufacturing and marketing authorization to add dosage and administration in which the dose is increased to the maintenance dose by one step (application to skin once-daily with dose of 9 mg as an initial dose and once-daily dose of 18 mg as the maintenance dose after 4 weeks, in addition to the current usage in a 3 step-up dosing regimen achieving a once-daily dose of 18 mg as the maintenance dose 12 weeks after the start of administration).

○ Neurokinin 1 receptor antagonist "Proemend for i.v. infusion"
In May 2015, we submitted approval application for additional indication of chemotherapy-induced nausea and vomiting in pediatric patients.

○ Short-acting β1 blocker "Onoact Intravenous Infusion 50mg / 150mg"
Phase Ⅱ/Ⅲ study for ventricular arrhythmias was started as a final clinical trial.

○ Tyrosine hydroxylase inhibitor "ONO-5371 / Metyrosine"
Phase Ⅰ/Ⅱ study for pheochromocytoma was started.

○ Phase Ⅱ trial of prostaglandin D_2 receptor antagonist "ONO-4053" has been conducted for the allergic rhinitis in Japan and Europe, but the development was discontinued due to no expected treatment effect.

< ONO-4538 (nivolumab), etc. >

○ Yervoy intravenous infusion (co-developed with Bristol-Myers Squibb(BMS))

In July 2015, the drug received the manufacturing and marketing authorization in Japan for the treatment of “unresectable or metastatic melanoma with disease progression”, so we expect NHI price listing soon.

○ Opdivo intravenous infusion (Japan / Korea / Taiwan)

・We submitted application for the manufacturing and marketing authorization for the treatment of "non-small cell lung cancer (NSCLC)," in Japan and Korea. In addition, squamous NSCLC and non-squamous NSCLC were applied at the same time in Korea. Also, in Japan, we filed application for squamous NSCLC in April, and submitted an additional indication application for the “treatment of patients with unresectable, advanced or recurrent NSCLC” in July, including the previous application.

・We began Phase Ⅱ trial for "urothelial cancer" in Japan. The trial is a part of a global clinical trial that had already been conducted.

・We submitted application to partially amend manufacturing approval for the treatment of “unresectable melanoma” in Japan (the usage for untreated melanoma before chemotherapy, and the additional application for the dosage and administration).

○ Opdivo intravenous infusion (EU / USA)

・ BMS received an approval of manufacturing and marketing authorization for "advanced melanoma" in EU.

・ BMS received an approval of manufacturing and marketing authorization for “squamous NSCLC" in EU.

・ The submission of additional application of Opdivo for "previously treated non-squamous NSCLC" was accepted in EU.

・ BMS, Our partner, newly began Phase Ⅲ clinical trial for "small cell lung cancer" in EU and USA.