Development Pipeline Progress Status (Summary)
in First Quarter of Fiscal Year Ending March 31, 2018

The followings summarize the changes in development pipeline status progress from the announcement of its consolidated financial results ended March 31, 2017 released on May 11, 2017. For the development pipeline progress status, please refer to pages 11 to 19 of the First Quarter Flash Report.

<Development status in the oncology field>

1. Development status in Japan

1) Kyprolis for Intravenous Infusion

Kyprolis obtained an approval for a partial change in approved items of the manufacturing and marketing approval (additional dosage and administration) for the treatment of relapsed or refractory multiple myeloma in May 2017. This approval is based on the results from ENDEAVOR study and allows Kyprolis to be used for combination therapy with one product at approximately a double dosage, 56 mg/m^2 (body surface area), in addition to the currently approved combination therapy with the two products.

2) ONO-7702 (encorafenib)/ONO-7703 (binimetinib)

ONO-7702, a BRAF inhibitor, and ONO-7703, a MEK inhibitor, both licensed from Array BioPharma (in the US), are now in two global Phase Ⅲ studies for the treatment of malignant melanoma and colorectal cancer as a combination therapy. Regarding the Phase Ⅲ study (including Japan) for malignant melanoma, the study result has been already made available. The products are now under a preparation for filing an application of the manufacturing and marketing approval.

3) Opdivo Intravenous Infusion

Phase Ⅱ study of Opdivo has started in Japan for the treatment of multiple myeloma. As Phase Ⅲ is ongoing in the US and Europe, the bridging study is planned in Japan in the future.

4) ONO-4059 (tirabrutinib)

Phase Ⅰ/Ⅱ study of ONO-4059, a Bruton's tyrosine kinase inhibitor, has started for the treatment of central nervous system lymphoma, an orphan disease.

5) ONO-7268MX1/ONO-7268MX2

While Phase Ⅰ studies of ONO-7268MX1 and ONO-7268MX2, both licensed from OncoTherapy Science, Inc. have been conducted for the treatment of hepatocellular carcinoma, the development of the products was discontinued due to the strategic reason.

2. Development status in South Korea and Taiwan

1) Opdivo Intravenous Infusion

Supplemental applications of Opdivo were filed in Taiwan for the indications of Hodgkin lymphoma, urothelial cancer and gastric cancer.

2) ONO-7702 (encorafenib)/ ONO-7703 (binimetinib)

ONO-7702, a BRAF inhibitor, and ONO-7703, a MEK inhibitor, both licensed from Array BioPharma, are now in two global Phase Ⅲ studies (including South Korea) for the treatment of malignant melanoma and colorectal cancer as a combination therapy.

3. Development status in the US and Europe

1) Opdivo Intravenous Infusion

In Europe, Opdivo was approved for additional indication of urothelial cancer. In the US, a supplemental Biologics License Application (BLA) was filed for the treatment of hepatocellular carcinoma.

<Development status in the non-oncology field>

1. Development status in Japan

1) Orencia for Subcutaneous Injection

The global Phase Ⅲ (including Japan) has started for the treatment of polymyositis and dermatomyositis.

2) Opdivo Intravenous Infusion

Phase Ⅰ/Ⅱ study has started for the treatment of sepsis.

3) ONO-2160/CD

While Phase Ⅰ study of ONO-2160/CD (a levodopa pro-drug) was conducted for the treatment of Parkinson's disease, the development of the product was discontinued due to less efficacy than expected.