Overview of Development Pipeline Progress Status

in Fiscal Year Ended March 31, 2018

<Development status of OPDIVO (nivolumab)>

- In September 2017, we got additional approval of OPDIVO for the treatment of gastric cancer in Japan. This is 6th approval for OPDIVO.
- OPDIVO has been approved for the treatment of 8 cancer types in US, 6 in Europe, 7 in South Korea and 8 in Taiwan.
- In Japan, the supplemental applications for OPDIVO have been filed for three indications; adjuvant melanoma, 1st line renal cell carcinoma (in combination therapy with YERVOY) and malignant pleural mesothelioma. These applications are expected to be approved in the near future.
- Regarding hepatocellular carcinoma (HCC)< 1st line >, esophageal cancer and small cell lung cancer (SCLC), the results of clinical trials will be available soon and be submitted to the MHLW within FY2018.
- European Medicines Agency accepted an application for OPDIVO plus YERVOY combination therapy for 1st line non-small cell lung cancer (NSCLC). The application is based on data from CheckMate -227 study. Likewise, we will file an application for this indication in Japan.
- Global Phase II / III study of OPDIVO started for colorectal cancer (CRC), in combination with existing drugs.
- An exploratory trial started for prostatic cancer in US and Europe.
- OPDIVO has been designated as subject drug for the treatment of biliary tract cancer under the Sakigake Designation System established by the MHLW. We are working with the regulatory authority to obtain an approval as early as possible.

<Major clinical trials of OPDIVO in combination with other Immuno-Oncology (I-O) compounds>

< Combination therapy of OPDIVO plus YERVOY(ipilimumab)>

- We have filed applications and been conducting Phase III trials for 9 cancer types; melanoma, RCC, NSCLC, SCLC, HNC, gastric cancer, malignant pleural mesothelioma, esophageal cancer and urothelial cancer.

< Combination therapy of OPDIVO plus other I-O compounds other than YERVOY>

- The clinical trial of OPDIVO in combination with anti-TIM-3 antibody newly started in the last 1 year.

- We are now conducting Phase I / II study in combination with relatlimab (anti-LAG-3 antibody), where the dosage and administration is also considered, based on the result of Phase I study.

- Clinical trials in combination with 8 different I-O compounds are ongoing. We are making efforts to find potential combination with OPDIVO showing higher efficacy to step forward, but have not yet identified it. As for IDO1 inhibitor, expected to be a promising compound, we have made a decision to discontinue ongoing Phase III trials for 3 cancer types; HNC, NSCLC and melanoma, judging from the following points in total; the failure in the trial of IDO1 inhibitor in combination with a competitive drug for melanoma indication, as well as the data of exploratory trial by BMS.

<Development pipeline in Japan (Oncology, other than OPDIVO>

- KYPROLIS was approved for the treatment of multiple myeloma in combination with lenalidomide (one product) in addition to the regimen for combination with two products, which had been approved in 2016.

- We submitted an application of encorafenib, a BRAF inhibitor and binimetinib, a MEK inhibitor, for the treatment of melanoma. Both compounds have been in-licensed from Array BioPharma, Inc.

- We submitted an application of metyrosine, a tyrosine hydroxylase inhibitor, for the improvement of accompanying symptoms of pheochromocytoma.

- Phase III clinical trials in combination with encorafenib and binimetinib for colorectal cancer newly started.

- Phase III study with ONO-7643 (anamorelin) is expected to finish in FY2018. We are planning to submit an application as quickly as possible after finishing the study. The target indication will be cachexia in all types of cancer.

- Clinical trial with ONO-4059, a BTK inhibitor, newly started for primary central nervous system lymphoma, rare carcinoma in Japan. Gilead Sciences, Inc., our partner, is pursuing clinical development overseas.

<Development pipeline in Japan (other than oncology)>

- Phase III studies of ORENCIA SC newly started for polymyositis and dermatomyositis.

- The application of ONO-1162 (ivabradine) is expected to be submitted for chronic heart failure within FY2018. In Japan, the number of patients with chronic heart failure is approximately 1.6 million. This product is indicated for those who have difficulties in lowering heart rate even when using beta blockers. Ivabradine is the first-in-class If channel inhibitor in Japan, having an effect of lowering heart rate without any influence on blood pressure by oral administration, and addressing high medical needs.

- Phase II study with ONO-2370 (opicapone) for Parkinson's disease is ongoing in Japan. As the results of Phase III study have already been available overseas, we will be able to file an application within FY2018, by bridging such results with the data of domestic Phase II study.

<Global development projects (other than OPDIVO)>

- We obtained exclusive rights to develop and commercialize encorafenib and binimetinib, in Japan and South Korea. Like in Japan, Phase III trials in combination with two products are ongoing in South Korea. For melanoma, an application of approval is now under preparation.

<About CheckMate-227 (for 1st NSCLC)>

- CheckMate -227 is comprised of two parts. Part1 includes both squamous NSCLC and non-squamous NSCLC. In Part 1a, there are 3 treatment groups; OPDIVO plus YERVOY combination group, OPDIVO monotherapy group and chemotherapy group in PD-L1 positive (≥1%) patients. In Part 1b, there are also 3 treatment groups; OPDIVO plus YERVOY combination group, OPDIVO plus chemotherapy group and chemotherapy group in PD-L1 negative (<1%) patients. In Part 2, there are 2 treatment groups; OPDIVO plus chemotherapy group and chemotherapy group across squamous and non-squamous types.

  In April 2018, the data from Part 1 was presented at American Association for Cancer Research (AACR). Among patients in whom TMB could be measured across PD-L1 expression, the data mainly available from this population with high TMB was compared between the combination therapy of OPDIVO and YERVOY group and chemotherapy group. The combination therapy of OPDIVO and YERVOY demonstrated a superior benefit for one of the co-primary endpoints, progression-free survival (PFS) to chemotherapy.

<American Society of Clinical Oncology (ASCO) 2018 annual meeting

– OPDIVO related subjects>

- As a whole, there are many subjects on biomarker exploratory study and combination therapy. Regarding combination therapy, subjects related to OPDIVO in combination with radiation therapy are increasing.
- The results of the long-term follow-up data in the verification studies will be presented.
- The results on the comparison of OPDIVO plus chemotherapy group versus chemotherapy group in PD-L1 negative patients in CheckMate-227 will be presented. In addition, the QOL analysis including safety data will be presented.
- The data on the combination therapy with OPDIVO and Nektar's compounds in the exploratory trials will be also presented.

<Phase II study of OPDIVO in malignant pleural mesothelioma>

- Overall response rate (ORR) was approximately 30% in the OPDIVO monotherapy with about 70% of disease control rate (DCR) were observed in 34 patients in Japan.