# Overview of Development Pipeline Progress Status in First Quarter of Fiscal Year Ending March 31, 2019 - Conference Call -

The followings summarize the status of development pipeline progress, of which details are described in pages 13 to 22 of the Consolidated Financial Results for the First Quarter of FY2019.

### <Development status in oncology area>

# 1. Products under NDA application

# 1.1 Opdivo Intravenous Infusion

Supplemental applications for Opdivo have been submitted for the treatment of malignant pleural mesothelioma and adjuvant therapy for melanoma (prevention of recurrence). In addition, an application of Opdivo has been filed as a combination therapy with Yervoy Intravenous Infusion for the first-line renal cell carcinoma.

# 1.2 ONO-7702 (encorafenib) / ONO-7703 (binimetinib)

Applications for ONO-7702, a BRAF inhibitor, and ONO-7703, a MEK inhibitor, have been submitted as a combination therapy of both products for the treatment of malignant melanoma.

### 1.3 ONO-5371 (metyrosine)

An application for ONO-5371, a tyrosine hydroxylase inhibitor, has been filed for the treatment of pheochromocytoma.

# 2. Progress from the announcement of the FY 2018 (May 10)

### 2.1 Japan

- Opdivo Intravenous Infusion / ONO-4687 (cabiralizumab) Phase II study has starred in Japan for the treatment of pancreatic cancer in combination of Opdivo and ONO-4687, an anti-CSF-1R antibody.

### - ONO-7705

Phase I study has started for the treatment of multiple myeloma and non-Hodgkin lymphoma with ONO-7705, an XPO1 inhibitor, licensed from Karyopharm Therapeutics Inc.

# 2.2 South Korea and Taiwan

 Opdivo Intravenous Infusion / ONO-4687 (cabiralizumab)
Phase II study has starred for the treatment of pancreatic cancer in combination of Opdivo and ONO-4687.

# 2.3 US and Europe

# - Opdivo Intravenous Infusion

Phase III study of Opdivo has started for the treatment of ovarian cancer in the US and Europe. In addition, Phase II study of Opdivo has started for the treatment of pancreatic cancer in combination with ONO-4687.

- ONO-7579

Phase I/II study of ONO-7597, a tropomyosin receptor kinase (Trk) inhibitor, for the treatment of solid tumor was discontinued for a strategic reason.

### <Development status outside oncology area>

# 1. Japan

- Onoact for Intravenous Infusion 50 mg / 150 mg

A supplemental application of Onoact was submitted for the treatment of refractory and urgent fatal arrhythmia (ventricular fibrillation and hemodynamically unstable ventricular tachycardia).

# 2. US and Europe

### - ONO-5788

Phase I study of ONO-5788, a growth hormone secretion inhibitor, was initiated in the US for the treatment of acromegaly.

# - ONO-8055

Phase I study of ONO-8055, a prostaglandin receptor (EP2/EP3) agonist, for the treatment of underactive bladder was discontinued for strategic reason.